

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

x

JAMES CURKIN, On Behalf of Himself and : Civil Action No. 05-CV-2827
All Others Similarly Situated, :
Plaintiff, : CLASS ACTION
vs. : AMENDED COMPLAINT FOR
HOWARD SOLOMON, et al., : VIOLATION OF THE FEDERAL
Defendants. : SECURITIES LAWS
:

x

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INTRODUCTION AND OVERVIEW

1. This is a class action for violation of the anti-fraud provisions of the federal securities laws on behalf of all purchasers of Forest Laboratories, Inc. (“Forest” or the “Company”) common stock during 8/15/02-9/1/04 (the “Class Period”), who were damaged thereby. Forest is a “specialty” pharmaceutical company that sells drugs (mostly requiring a physician’s prescription) through a salesforce which “details,” *i.e.*, promotes, Forest’s drugs directly to physicians to persuade them to prescribe Forest’s drug products to their patients. For many years, Forest emphasized the sale of generic drugs, a very low-margin business. However, during the 90s, Forest transitioned into a branded drug company, selling patented drugs which had marketing exclusivity periods, allowing Forest to sell much higher priced and more profitable drugs. Forest scored a great success following the 8/98 launch of Celexa (Citalopram), a patented selective serotonin reuptake inhibitor (“SSRI”) drug which Forest licensed from a Danish company (Lundbeck) for sale in the United States. Celexa (known as Cipramil in Europe), was approved by the U.S. Food and Drug Administration (“FDA”) *only* to treat depression in adults, *i.e.*, persons 18 years of age or older. Celexa’s great success boosted Forest’s revenues (up five times by 02) and profits (up from \$37 million to \$338 million for Forest’s fiscal year ended 3/31/02) and thus its stock price, which quadrupled from \$10 to \$40 by early 02.¹ However, Celexa’s great success also turned Forest into a “one-drug” company as, by 00-01, 70%-80% of Forest’s sales and profits depended upon sales of this one drug alone.

2. As a patented drug, Celexa had a five-year exclusive marketing period, originally to last until 9/03, after which “generic” Celexa would flood the market causing prices for the

¹ Forest’s stock split 2-for-1 in 1/03. All stock prices herein are split-adjusted.

drug to plunge. Since Celexa's exclusive marketing period, which allowed Forest to charge very high profitable prices for the drug, was to expire in 9/03, Forest's strategy was to work with its licensor Lundbeck to develop a follow-on patented drug, Lexapro (Escitalopram) – which contained the same active ingredient as Celexa and therefore would be essentially the same as Celexa, but with sufficient claimed differences to justify the follow-on drug being granted a patent and its own period of market exclusivity extending for years beyond when Celexa would “go generic.” This would also allow Forest to credibly claim that the new Lexapro drug was superior in performance to Celexa in treating depression so as to justify physicians continuing to prescribe Lexapro to patients notwithstanding its much higher price, compared to the essentially identical generic Celexa. Once Lexapro was approved for sale by the FDA, Forest would stop promoting Celexa, stop paying its salesforce to sell Celexa and have its salesforce, *i.e.*, “detail men,” intensely work on physicians to get them to switch their Celexa patients to the new drug – Lexapro – so that after Celexa “went generic” and prices for it plunged, Forest could continue to charge very high and profitable prices for what was essentially the same drug – Lexapro – during Lexapro’s five-year exclusive marketing period. If Forest was not able to get physicians to switch 70%-80% of their Celexa patients to Lexapro before Celexa went generic, Forest’s profits would be very adversely affected, as would its stock price.

3. The FDA approves prescription drugs only for specified, limited uses. Drug companies are only permitted to promote or market drug products for those specified, limited uses, *i.e.*, they are forbidden from promoting or marketing drugs for any non-approved use. However, physicians are permitted to prescribe a drug *for any use they think beneficial for the patient as long as the drug has been approved by the FDA for any use*. This prescription practice is known as “*off-label*” use of a drug. If physicians are persuaded that an approved drug

can be beneficial to a patient for an unapproved use, they can and will prescribe the drug for that “off-label” use. Such off-label use of a drug can constitute a significant portion of a drug’s use and thus boost a drug company’s revenues and profits far higher than if the drug were prescribed only for permitted uses, giving drug companies a strong economic incentive to market and promote “off-label” use, even though this is illegal.

4. While Celexa had only been approved for use in adults 18 years of age or older, and Lexapro would have only the same limited permitted use, Forest’s executives knew that if they could get physicians to prescribe Celexa and then Lexapro *for childhood and adolescent depression*, this would materially increase Forest’s revenues and profits, as there are approximately four million children and adolescents in the U.S. suffering from depression, and during 02-03, some 11 million SSRI prescriptions were written annually for treatment of depressed children or adolescents. Only one anti-depressant drug (Prozac) had been approved for prescription use for children/adolescents. So if Forest could market Celexa/Lexapro to treat depressed children/adolescents, it would vastly increase the size of the market for those drugs and the revenues and profits that Forest could obtain from selling them. However, because promotion of Celexa/Lexapro for childhood/adolescent depression was illegal due to concerns of increased suicidality in that population with SSRI drug use, Forest had to be very circumspect in this regard and keep its off-label promotional activities secret as, if Forest were caught engaging in off-label promotion of Celexa, Lexapro or any other drug, it could face severe government action, including large fines, as well as very negative publicity, which would hurt its business and its stock price.

5. In order for the vital Celexa/Lexapro product transition strategy to succeed, Forest wanted Celexa’s exclusive marketing period to last as long as possible so that when Forest was

permitted by the FDA to begin actively marketing Lexapro, Forest's salesforce would have as long as possible to get physicians to switch their Celexa patients to Lexapro before generic Celexa swamped the market, which would inevitably result in much lower prices for generic Celexa, destroying the high profit margins Forest had enjoyed from selling that drug. Forest had filed with the FDA for permission to market Lexapro for adults aged 18 years or older in 3/01. By the Spring of 02, Forest's efforts to achieve FDA approval of Lexapro had reached the point where Forest anticipated it would receive FDA approval to market Lexapro in 8/02-9/02.

6. Thus, in order to extend Celexa's exclusive marketing period by six months and also create studies that its salesforce could use to promote and market Celexa/Lexapro for treatment of childhood/adolescent depression, Forest (and its licensor, Lundbeck) undertook to exploit a provision in U.S. law that permitted Forest to obtain an automatic six-month extension of Celexa's exclusive marketing period by performing studies on Celexa in pediatric care – funding such studies and having their employees involved in conducting those studies so they could have knowledge of how the studies were progressing, influence the outcome of the studies and control the public release and publicizing of such studies.

7. By late 01, Forest and Lundbeck had managed to complete one pediatric study on Celexa, which purportedly showed that the drug improved depression in children/adolescents, and wanted to publicize this study so that Forest's salesforce would have materials to use to market Celexa and Lexapro, upon its upcoming introduction, for off-label under-18-years-of-age use. Anticipating FDA approval to market Lexapro later in 02, Forest, in order to condition the physician-prescribing community and influence securities analysts and investors, arranged for a Celexa pediatric study to be presented at the Annual Meeting of Neuropsychopharmacologists in 12/01 and *to publicize the presentation of that study by issuing a press release entitled “Results*

of escitalopram and Celexa studies presented at major scientific conference.” According to Forest’s 12/13/01 release:

Forest Laboratories, Inc. announced that clinical study results were presented today at an annual meeting of neuropsychopharmacologists, including . . . a pooled analysis of flexible-dose studies demonstrating that patients with major depressive disorder treated with either escitalopram or Celexa™ (citalopram HBr) showed significantly greater improvement than patients receiving placebo, ***and a study demonstrating that Celexa may significantly reduce depression in adolescents and children.***

* * *

“Forest is committed to the development of effective medications for the treatment of depression, ***and the results of these studies are especially encouraging,***” said Howard Solomon, chairman and chief executive officer, Forest Laboratories.

* * *

Celexa in the Treatment of Pediatric Depression

Celexa was shown to reduce symptoms of depression in adolescents and children with major depressive disorder to a significantly greater extent than placebo in a randomized, double-blind, placebo-controlled, flexible-dose study The study also showed that Celexa was well tolerated. . . .

This study is significant because few studies involving any antidepressant have shown efficacy compared to placebo in the treatment of depression in children and adolescents,” said Karen Dineen Wagner, MD, PhD, Department of Psychiatry and Behavioral Sciences, University of Texas Medical Branch at Galveston, and the study’s lead author. ***Citalopram is now one of the few therapies for which we have data showing safety and efficacy for this population.***”

8. As Forest’s Lexapro marketing launch date approached during 02, in order to continue to condition the physician-prescribing community and influence securities analysts and investors, Forest again arranged for this favorable pediatric study to be publicly presented, this time at the Annual Meeting of the American Psychiatric Association in Philadelphia on 5/18-23/02. The Forest-sponsored and controlled study was entitled “A Randomized, Placebo-

Controlled Trial of Citalopram [Celexa] for the Treatment of Major Depression in Children and Adolescents." The study, of 83 children aged 7-11 and 91 adolescents aged 12-17, concluded:

In this population of children and adolescents, treatment with citalopram reduced depressive symptoms to a significantly greater extent than placebo treatment and was well tolerated.

* * *

Citalopram, an SSRI shown to be effective in the treatment of depression in the adult population, *appears well suited for use in children and adolescents because it has a favorable side effect profile, a low potential for drug-drug interactions, and is relatively safe in overdose, which is of concern in this population.*

This study then observed:

It is tempting to speculate that similar clinical results would be achieved in children and adolescents treated with the recently developed single isomer compound escitalopram [Lexapro], since the serotonin reuptake activity of citalopram is attributable to its S-isomer. . . .

The study concluded:

[C]italopram treatment significantly improved depressive symptoms compared with placebo within 1 week in this population of children and adolescents. No serious adverse events were reported. . . . These findings further support the use of citalopram in children and adolescents suffering from major depression.

9. In 8/02, Forest received FDA permission to market Lexapro *to adults only.*

Lexapro's formal marketing launch was set for 9/05/02. In 7/02, Forest issued a release that it had obtained a six-month extension of Celexa's exclusive marketing period due to the completion of a successful pediatric care study involving that drug. Due to Forest's prior publicizing of a successful study of Celexa in pediatric populations, the implication was that this study submitted to the FDA was successful. By reason of this study, the Celexa exclusive marketing period, which was to have expired in 9/03, was extended until 2/04, which was important to give Forest as much time as possible to persuade physicians to transition their depressed patients from Celexa to Lexapro and *also to give Forest's salesforce a study to use in*

the promotion of Celexa and its look-alike Lexapro (to be introduced in the next few weeks), even though they were approved only for adults, i.e., persons over 18 years of age.

10. To further publicize its favorable pediatric care Celexa/Lexapro study, Forest again arranged for a researcher from that study, Dr. Karen Wagner, to present the results of the study at a major neuropsychopharmacology conference in late 8/02, *just a few days before the official marketing launch of Lexapro on 9/5/02*, helping to arrange for publicity for that presentation. The presentation was reported in *Pediatric News*, a medical publication distributed to thousands of physicians, including those specializing in pediatric care. At that conference, Dr. Wagner, on Forest's behalf, again claimed that the pediatric study of 83 children aged 7-11 and 91 adolescents aged 12-17 demonstrated substantial efficacy in the studied population without significant adverse side-effects. Having now taken repeated steps to get this pediatric study into the public domain to influence securities analysts and investors, as well as the physician-prescribing community, Forest had its salesforce promote Celexa and Lexapro to physicians for use with childhood/adolescent patients.

11. Then, shortly after Lexapro was brought to market in 8/02, Forest again arranged for publicity indicating that the active ingredient shared by Celexa and Lexapro was effective in treating depression in minors with minimal adverse side effects *in two separate studies*, a “*booster shot*” for marketing the drug as well as for Forest's stock. Forest arranged for the publication of the following article concerning two studies it and its licensor, Lundbeck, had performed on children and adolescents in the 12/1/02 edition of *Clinical Psychiatry News*, which stated:

Citalopram may help children's depression. (Minimal Side Effects).

... Citalopram may improve symptoms of major depressive disorder with minimal side effects in children and adolescents, according to two studies

presented at the Congress of the Collegium Internationale Neuro-Psycho-pharmacologicum.

The antidepressant was effective and well tolerated in a double-blind, placebo-controlled, flexible-dose study of 83 children and 91 adolescents, said Dr. Karen Wagner of the University of Texas, Galveston. Similar results were obtained in a retrospective study of 76 South African children and adolescents that considered the safety and efficacy of the drug relative to other selective serotonin reuptake inhibitor antidepressants. . . .

The studies are among the first to consider the safety and efficacy of antidepressant agents in children, noted Dr. Duncan Rodseth of Lundbeck.

The 8-week Texas trial compared 20-40 mg of citalopram with placebo in children and adolescents aged 7-17 years with major depressive disorder who had exhibited symptoms for at least 4 weeks prior to enrollment.

* * *

In the South African study investigators reviewed data on 76 children and adolescents being treated with citalopram for an average of 102 days at doses ranging from 5 to 30 mg, Dr. Rodseth said. ***Minimal adverse effects were observed, he said.***

12. During the Class Period, Forest indicated to the investment community that it did not engage in promoting its products for “off-label” uses, stating that “[m]arketing our products requires us to scrupulously inform physicians about those products . . . [in] communicat[ions] with physicians [Forest] must always be accurate” and “not . . . abuse our access to physicians.” However, during the Class Period, while Forest was proclaiming and publicizing the success of its Celexa/Lexapro transition and the success of the new Lexapro drug to the financial community, it was ***illegally promoting*** Celexa/Lexapro for “off-label” childhood/adolescent use and ***concealing*** its own study data (as well as other data available to it) that indicated that SSRI anti-depressant drugs (including Celexa/Lexapro) ***did not work in children/adolescents and were associated with increased suicidality in that population.*** Forest did this because it knew that any widespread public realization that its SSRI anti-depressant drugs, *i.e.*, Celexa/Lexapro, were associated with ***increased suicidality of anyone*** – children,

adolescents or adults – **would have a major negative impact on prescription trends for Forest’s SSRI drugs, which would hurt investor perceptions of Forest’s business, products and future growth and thus hurt its stock price.**

13. To compound this deceit, during the Class Period, Forest indicated to the investment community that it released all drug studies, favorable or not. It stated “**we always release results as soon as we get them,” “[w]hen there are [sic] any study that’s material at Forest, we release results as soon as we can,” and “if it’s not in our favor, it’s not in our favor.**” In publicizing its two short, small and purportedly successful Celexa/Lexapro pediatric use studies in 12/01, 5/02, 7/02, 9/02 and 12/02 and then using them to improperly promote Celexa/Lexapro for “off-label” childhood/adolescent use, Forest was concealing from physicians, patients, parents, financial markets and even Forest’s own salesforce that, during 96-02, Lundbeck, the developer and licensor of Celexa/Lexapro to Forest, had conducted a **large, six-year study of Celexa’s efficacy and safety involving over 422 children and adolescents which had demonstrated that there was no pre-adult efficacy from the drug and – worse yet – that there were significant adverse side-effects, including increased suicidality!** Forest’s creation, publication, promotion and circulation of the “successful” Celexa/Lexapro pediatric studies, while concealing the larger, longer, negative study, was deceptive conduct, as were Forest’s statements that Forest’s strong Class Period financial results reflected “**positive physician response**” to Lexapro and a “**strong uptake in Lexapro prescription volume,**” when a material portion of the drugs’ sales were due to Forest’s improper promotion of “off-label” childhood/adolescent use while concealing its lack of efficacy and increased suicidality in that population. As a result of these false statements, concealments and improper actions, Celexa’s exclusive marketing period was extended by six months. As Lexapro was formally launched in

9/02, *Celexa/Lexapro became the fourth largest anti-depressant drug prescribed for adolescents*, with such “off-label” use contributing approximately 10% of Forest’s Celexa/Lexapro revenues and profits during the Class Period.

14. As stated earlier, as Forest faced the end of Celexa’s exclusive marketing period, which it knew would soon bring massive generic competition, *i.e.*, a flood of Celexa generics at cheap prices, it was imperative that Forest get physicians to transition as many Celexa patients as possible to Celexa’s patented successor – Lexapro – as quickly as possible. For this to occur, two things were indispensable. First, Lexapro had to be presented as sufficiently differentiated from Celexa to justify patent protection and its own new five-year period of marketing exclusivity. In addition, Lexapro had to be presented as sufficiently *superior to its predecessor Celexa in treating depression* to justify physicians prescribing it at high prices even after low-priced, generic Celexa became available. Thus, Forest constantly described Lexapro as different from and functionally superior to Celexa in order to justify (i) patent protection and a five-year period of marketing exclusivity for Lexapro, as well as (ii) a higher price for Lexapro compared to the soon-to-arrive Celexa generics, greatly boosting Forest’s reported revenues and profits during the Class Period. To this end, during the Class Period, Forest said Lexapro was “*quite different*” from and “*superior[]*” to Celexa, as it had “*greater effect*” and was “*more efficacious*.” According to Forest, this “*clinical differentiation*” was a main “*selling point to physicians*” to get them to “*upgrade*” patients from Celexa to Lexapro. In fact, so purportedly superior was Lexapro to Celexa that Forest stated it was “*not necessary*” to initiate a study to compare Lexapro to Celexa. In fact, however, these representations of Lexapro differentiation and superiority were false and misleading, as Lexapro was pharmacologically virtually identical to Celexa and its efficacy in its permitted patient universe for treatment of depression was not

materially better than Celexa, which was why Forest did not want to perform any head-to-head Celexa/Lexapro study.

15. As noted above, by 01, Forest was a one-product company with between 70%-80% of its revenues and profits coming from Celexa sales, which had boosted Forest stock to all-time high levels of \$40-\$41 per share in 7/01. However, as a result of investors' concerns over Forest's dependence on Celexa/Lexapro, after reaching its then all-time high of \$41.16 in 7/01, Forest's stock moved "sideways" for months and, by the Spring of 02, was trading in the \$30-\$40 per share range, reaching a low of \$32.12 on 7/11/02, *just before* Forest announced that a successful pediatric study of Celexa had enabled it to obtain a six-month extension of Celexa's exclusive marketing period, which study, of course, created hope that Celexa/Lexapro could ultimately be approved for childhood/adolescent use, thus greatly expanding the market for, revenues, and profits to be obtained from those drugs.

16. To continue to achieve the type of revenue and profit gains Forest had reported in 98-01, and which were necessary to push Forest's stock price higher, Forest needed to develop and market another "*blockbuster*" drug, *i.e.*, a high-revenue, high-profit patented prescription drug. Forest's best hope in this regard was a drug known as Memantine²/Namenda, a drug that Forest and its licensing partner (Merz from Germany) were developing to treat Alzheimer's disease, a potentially huge market in the U.S., where few approved treatments then existed. In 11/02, Forest published a study showing Memantine/Namenda had modest efficacy with *moderate/severe* Alzheimer's disease, at least in slowing progression of the disease. Based on

² Pronunciation rhymes with "Oh my darling, Clementine."

Forest's FDA filings for Memantine/Namenda, it was anticipated that Forest would receive FDA approval to market that drug for moderate/severe Alzheimer's disease in 03.

17. As Forest received its six-month Celexa exclusive marketing extension, publicized the success of Celexa and Lexapro in treating pediatric depression without adverse side effects, successfully introduced Lexapro and was persuading physicians to switch large numbers of patients from Celexa to Lexapro due to its purported superior efficacy in treating depression, and anticipated FDA approval to market Memantine/Namenda for moderate to severe Alzheimer's disease during 03 and favorable results from an ongoing Memantine/Namenda study on mild/moderate Alzheimer's disease, Forest's stock took off. After closing at \$34.12 on 7/11/02, Forest's stock soared higher, reaching \$54 in late 11/02 and \$61.35 by mid-6/03. As Forest's stock soared to these higher prices, its officers and directors took advantage of the increasing artificial inflation in the price of the stock by bailing out, *selling some 2.27 million shares of Forest stock they owned, pocketing \$111 million in illegal insider trading proceeds.*

18. Because by far the largest market for Forest's new Alzheimer's disease drug would be in the *mild* category of the disease (45+% of cases), during 02 and 03, Forest told analysts that it was conducting trials of Memantine/Namenda for mild/moderate Alzheimer's disease, and that it anticipated favorable study results and expected later FDA approval for this expanded use of Memantine/ Namenda. However, in 6/03, while Forest was in the midst of seeking FDA approval for Memantine/Namenda for moderate/severe Alzheimer's, Forest was forced to publish the results of the Memantine/Namenda mild/moderate study it had previously told analysts it was conducting and reveal that that study *had failed* to show any efficacy in treating mild/moderate Alzheimer's disease, a stunning disappointment. This development

caused Forest's stock to plunge by over \$8 per share from \$61.19 on 6/18/03 to \$52.85 on 6/19/03 – ***on large volume of 14,523,300 shares, the largest one-day stock price decline in Forest's history!*** Shortly thereafter, Forest reported an apparent slowing of SSRI anti-depression drug prescriptions in the summer of 03, which resulted in Forest's stock falling to as low as \$41.85 on 8/20/03, ***wiping out most of the stock's large gains from the beginning of the Class Period when Forest had announced FDA approval of Lexapro and caused its small, successful study regarding the pediatric use of Celexa to be publicized.*** This sharp collapse in Forest's stock graphically demonstrated to Forest's executives that the investment community would not tolerate disappointing news regarding Lexapro prescriptions or Memantine/Namenda development. As Forest's stock plunged lower, Forest's insiders stopped their insider selling.

19. During 9/03 and 10/03, an FDA panel and then the FDA itself formally approved Memantine/Namenda for moderate/severe Alzheimer's disease. Then, after a Pfizer study was publicized in 8/03 showing its SSRI drug Zoloft – the largest selling SSRI anti-depressant drug in the world and Celexa/Lexapro's most important competition – was ***beneficial to adolescents with no increased suicide risk,*** Forest quickly publicized its own study on 12/10/03, representing that ***Lexapro was as effective as Zoloft.*** Given Forest's prior publicizing of studies showing that its Celexa/Lexapro drugs were effective in treating children and adolescents without adverse side effects, this new Forest study indicating that Lexapro was as effective as Zoloft was very significant to investors, as well as the physician-prescribing community. Forest's stock again began to move higher.

20. Based on the FDA's 10/03 approval of the sale of Memantine/Namenda for moderate/severe Alzheimer's disease, in 10/03-2/04, Forest began to manufacture Memantine/Namenda to stock drug wholesalers and pharmacies with the drug, while intensively

training its salesforce for Memantine/Namenda promotion, knowing that it would be permitted to begin to actively market, *i.e.*, detail, Memantine/Namenda on or about 3/1/04. In anticipation of the 3/1/04 formal marketing launch of Memantine/Namenda, on 1/7/04, to condition the physician-prescribing community and impress investors and analysts, Forest publicized a new study that indicated that Memantine/Namenda had efficacy for patients suffering from mild/moderate Alzheimer's disease, telling analysts and investors that this study would be sufficient to obtain FDA approval to market the drug for that purpose, assuring them that it could obtain FDA approval to market Memantine/Namenda for mild to moderate Alzheimer's disease based on one successful study. Forest told analysts and investors – as well as the physician-prescribing community – that, as a result of this successful study, it would file a supplemental New Drug Application ("sNDA") with the FDA to approve the use of Memantine/Namenda for the treatment of mild/moderate Alzheimer's disease in mid-04. This successful study was especially significant coming after Forest had released the disappointing "failed" prior study just months earlier in 6/03. Forest told investors and analysts that filing this important sNDA would be a simple task, "*[w]e basically just have to put the package together for all of the trials that have been done . . . and file that . . . a six-month process to get that filing done.*" In fact, the one positive study defendants could submit to the FDA was more than outweighed by the two negative studies that had been conducted. As such, Forest was unable to complete the filing in the timeframe stated by defendants and, when it was finally filed, Forest's application for the use of Namenda for mild to moderate Alzheimer's was flatly denied by the FDA. As a result of this extremely positive news, Forest stock skyrocketed from \$61.50 on 1/6/04 to \$71.09 on 1/7/04, on huge volume of 9.9 million shares – *Forest's stock's largest one-day increase in history* – as this new information indicated that Memantine/Namenda would, after all, end up being available

for prescription to the entire spectrum of Alzheimer's disease patients – mild, moderate and severe – a gigantic market – giving the drug a multi-billion dollar potential in a time frame dictated by the mid-04 filing of an sNDA with the FDA Forest indicated it would make.

21. Then, on 2/23/04, *just eight days before the 3/1/04 formal marketing launch* of Memantine/Namenda for moderate/severe Alzheimer's disease, Forest again *voluntarily publicized* the results of its new successful mild/moderate Memantine/Namenda test it had already released on 1/7/04. This was done to further impress investors and analysts and to condition the physician-prescribing community for Forest's planned promotion of Memantine/Namenda for mild/moderate Alzheimer's and so that its salesforce would have materials to direct physicians to, or to provide to physicians to get them to prescribe Memantine/Namenda "off-label" for mild/moderate Alzheimer's.

22. As a result of these favorable representations during the Fall of 03, *i.e.*, that Lexapro was sufficiently superior to Celexa to justify a premium price and sufficiently different in composition and action to justify its own patent protection and period of marketing exclusivity, that Forest was successfully transitioning large numbers of Celexa patients to Lexapro because of Lexapro's superior performance in treating depression, that Lexapro was as effective as Zoloft (which had recently been reported by Pfizer to be beneficial in treating depressed children and adolescents without any increase in suicidality), and that Memantine/Namenda had been approved by the FDA for prescription use in moderate/severe Alzheimer's disease patients and had now proven efficacious for mild/moderate Alzheimer's disease patients leading to a mid-04 sNDA and anticipated FDA approval thereafter, *Forest's stock soared to its highest levels in history, skyrocketing from \$41.85 on 8/20/03 to a Class Period closing high of \$77.59 on 1/26/04 – an 85% increase in the stock price and a \$13-\$14*

billion increase in aggregate market value in just five months. As Forest's stock soared to these higher, increasingly inflated levels, Forest's executives resumed their insider bail-out, *selling over 2.9 million shares of their Forest stock between 10/03-2/04 for almost \$200 million, including 1.7 million shares for \$134 million at between \$72-\$77.42 per share in 1/04-2/04, as Forest's stock traded at or near its historical peak!*

23. Thus, by late 1/04, Forest executives had driven Forest's stock to by far its highest price in history by improperly promoting and marketing Celexa/Lexapro and Memantine/Namenda for off-label uses, while concealing studies they had or were aware of that contradicted such off-label uses and Forest's claims of efficacy, lack of side effects and safety for those drugs, thus misrepresenting the uniqueness, quality and efficacy of the Company's two most important drug products to physicians, caretakers, patients, Forest's stockholders, securities analysts and investors. However, in late 1/04, information began to enter the market indicating that many of Forest's prior statements had been false and misleading and that Forest had engaged in deceptive or misleading conduct, resulting in the artificial price inflation starting to come out of Forest's stock price.

24. On 1/29/04, Forest was forced to reveal that the U.S. Attorney's office in Philadelphia, acting on behalf of the Inspector General for the U.S. Office of Personnel Management (which has oversight jurisdiction of the U.S. government's massive healthcare plans covering some 10 million federal employees and their dependants), had subpoenaed Forest's records *concerning over-aggressive marketing of its drugs, including Celexa/Lexapro.* When interviewed by the media, the Assistant U.S. Attorney in charge of the investigation stated that "*the office of the inspector general gets involved when there's fraud, when you cross over to misleading, deceptive or false statements or when there are kickbacks involved in*

connection with the marketing.” Just a few days later, on 2/2/04, an FDA panel held a hearing regarding the risk of increased suicidality among adolescents taking anti-depressant SSRI drugs, *including Celexa/Lexapro, and, based on the evidence presented at the hearing, then quickly took the highly unusual step of urging that strong suicide warnings immediately be placed on the labels of SSRI anti-depressant drugs, including Celexa/Lexapro, even before formal FDA review of this issue.* Upon these initial revelations that Forest had been illegally or fraudulently promoting and/or marketing its drugs for off-label uses and that its Celexa/Lexapro drugs were so associated with increased suicidality as to require an immediate enhanced warning label, its stock began to decline, and the artificial inflation in the price of the stock began to dissipate, as the truth began to enter the market, damaging class members who had previously purchased the stock.

25. In 3/04, the FDA warned U.S. doctors of an increased risk of suicidality with SSRI drugs, specifically identifying Celexa and Lexapro. At the same time, Lundbeck revealed that it had *placed a prominent suicide warning on the Celexa drug in Europe for years*, although no similar disclosure or warning had been made by Forest in the U.S. Forest’s stock price continued to fall. In late 4/04, an extremely prestigious British medical organization’s Committee on Safety of Medicines (“CSM”) published an important study documenting *increased suicidality among adolescents taking SSRI drugs, exposing the fact that certain drug companies selling such drugs, including Forest, had concealed studies they had previously performed showing that those drugs had no efficacy with children/adolescents but increased suicidality.* The British study, which received wide-spread publicity, specifically concluded that Celexa had not demonstrated efficacy in treating depressed children/adolescents and carried an increased rate of self-harm compared with a placebo, *i.e.*, an unfavorable

risk/benefit balance. A major British medical publication, *The Lancet*, reported on the study and stated as to Celexa that the CSM review provided

data from two unpublished trials on 422 participants with major depressive disorder aged 7-18 years old (citalopram study 1 and 2). Efficacy data from these trials were limited, but suggested that *citalopram [Celexa] was unlikely to produce a clinically important reduction in depressive symptoms . . . In terms of safety, citalopram increased the risk of attempting suicide . . . With no good evidence for efficacy and the potential for increasing the risk for suicide, the risk-benefit balance is unfavorable.*

Forest stock continued to decline, falling to as low as \$63.25 on 4/23/04, a decline of 18% from its Class Period closing high price of \$77.59 on 1/26/04, before this series of adverse revelations began and additional artificial price inflation came out of the stock as more truth entered the market.

26. As part of its ongoing effort to counter adverse publicity concerning Celexa/Lexapro and differentiate Celexa/Lexapro from other SSRI depression drugs and their association with suicidality, Forest had arranged for the 6/04 edition of *The American Journal of Psychiatry* to publish the study Forest had conducted in 01 – and earlier publicized in 12/01, 5/02, 7/02, 9/02 and 12/02 – purportedly showing that Celexa/Lexapro was efficacious in treating adolescent depression. However, within days after the 6/04 edition of *The American Journal of Psychiatry* carrying this article was circulated, *The New York Times* published an explosive exposé stating that the Forest-sponsored *American Journal of Psychiatry* article had failed to include or present a much larger, more comprehensive study conducted by Forest/Lundbeck during 96-02, which demonstrated that *Celexa was not only not efficacious for adolescent depression, it produced increased suicidality, and that Forest had concealed this study from The American Journal of Psychiatry and that Forest/Lundbeck had not previously publicly released or publicized this adverse study as it had favorable studies regarding Celexa/Lexapro in treating depression in children/adolescents.* As a public uproar erupted over

this deception by Forest, British health authorities demanded that Lundbeck/Forest surrender the secreted Celexa adolescent study and Forest's stock continued to plummet. Now exposed, on 6/24/04, Forest was forced to reveal *what it claimed was a "recently completed," second Celexa/Lexapro study it had which also showed that Celexa/Lexapro was not efficacious in treating adolescents!* Forest stock continued to fall to as low as \$57.10 on 6/28/04, which securities analysts attributed to adverse revelations concerning Celexa/Lexapro and adolescent suicidality and the resultant slowing in growth of SSRI prescriptions by physicians.

27. On 6/29/04, Eliott Spitzer, the Attorney General of New York, requested that Forest provide all documents it had regarding concealed clinical trials or tests and "off-label" promotional activities for its drugs – a request which followed recently highly publicized legal action by Spitzer's office against GlaxoSmithKline for fraudulent marketing of its SSRI drug – Paxil – for adolescent use and GlaxoSmithKline's concealment of studies it had performed or had showing that Paxil did not work with adolescents and caused increased suicidality.

28. On 8/5/04, *The Wall Street Journal* reported that in mid-7/04, the FDA had concluded that its review of 25 prior clinical studies showed a clear link between SSRI anti-depressant drugs and an increase in adolescent suicidality, *including Forest's Celexa/Lexapro drug.* During 7/04-8/04, a number of securities analysts that followed Forest cut their ratings on Forest's stock, as well as their growth forecasts for Forest's revenues and profits, due to the negative publicity surrounding Forest and SSRI drugs, including Celexa/Lexapro, which was resulting in increased physician reluctance to prescribe the drug and slowing SSRI prescription growth – including Celexa/Lexapro. Forest's stock continued to fall lower as the artificial inflation continued to come out of the stock due to these negative revelations, exposing Forest's

prior false and misleading statements and illegal and deceptive conduct, and causing Forest's stock price to drop to as low as \$44.44 on 8/6/04.

29. By 9/1/04, investors and analysts realized that despite Forest's prior representation that it would file an sNDA for Memantine/Namenda for the treatment of mild/moderate Alzheimer's disease by mid-04, Forest had not filed the sNDA and thus Memantine/Namenda would not be approved for active marketing or sale for use in patients with mild/moderate Alzheimer's disease, *at least not in the timeframe that Forest had previously indicated*, thus restricting the available market for that drug and the potential Forest revenues and profits from that drug. Later, Forest did file an sNDA for Memantine/Namenda for mild/moderate treatment of Alzheimer's, but the application was denied by the FDA as the drug did not produce statistically significant results.

30. On 9/2/04, Forest stock traded as low as \$41.10. Over the next few weeks, slowing SSRI prescription growth due to suicidality concerns surrounding those drugs (including Celexa/ Lexapro) and Forest being forced to agree to a settlement with the New York Attorney General in order to avoid legal action by promising that it would in the future post all clinical studies, favorable or unfavorable, on a publicly accessible Web site, including studies related to Celexa/Lexapro, caused Forest's stock price to further decline, taking more artificial price inflation out of the stock, finally reaching a low of approximately \$36.10 on 11/22/04. Forest's stock essentially completed a "round-trip" from its low of \$32.12 on 7/11/02, at the outset of the Class Period and the fraudulent scheme to deceive investors and artificially manipulate and inflate Forest's stock price higher, which succeeded in pushing the stock to an all-time high and grossly inflated closing price of \$77.59 on 1/26/04, before the series of adverse revelations over the next few months brought forth accurate and truthful information that exposed that Forest had

been lying about the qualities and capabilities of its two most important drug products, *i.e.*, Celexa/Lexapro and Memantine/Namenda, while concealing its improper activities in promoting and marketing those drugs for off-label uses to boost Forest's reported revenues and profits.

31. Investors who purchased Forest stock during the Class Period suffered damages, as they purchased the stock at artificially inflated prices and the stock later declined as the true facts came out in a series of negative revelations. However, Forest's top insiders, who participated in, perpetuated or benefited from this scheme to defraud, did not do nearly so badly for themselves. *During the Class Period, Forest's top officers and directors, including those named as defendants herein, sold 5,393,980 shares of Forest stock at as high as \$77.42 per share, pocketing over \$314 million in illegal insider trading proceeds. Remarkably, these top insiders unloaded 1,788,000 shares of Forest stock for \$133 million during 1/04-2/04 at between \$72 and \$77.42 per share, just as Forest stock hit its all-time high and grossly inflated price due to defendants' illegal conduct.*

32. On 2/1/05, it was reported in *USA Today* that:

Kids' antidepressant use declines

Massive publicity about antidepressants causing suicidal behavior in children is prompting more parents and doctors to hesitate longer or "just say no" to giving kids the pills, suggest new prescription records and interviews with doctors.

In the last three months of 2004, the rate of patients under 18 who got antidepressant prescriptions dropped 16% compared with the same time period in 2003 There was a 19% drop in the third quarter of 2004 compared with the same time frame in 2003.

In October, the Food and Drug Administration ordered "black box" labels, the most severe warning, on all antidepressants.

33. The statements made by Forest or on behalf of Forest between 8/02-9/04 were false and misleading when made in their own right and for failing to disclose the following adverse facts necessary to make the statements made not misleading:

- (a) Forest was aware of a large multi-year study of Celexa for treating childhood/adolescent depression performed by Lundbeck with Forest's knowledge, consent and input, which showed that Celexa was not efficacious in that population and increased suicidality.
- (b) Lexapro was not superior to or more efficacious than Celexa in treating depression in adults 18 years or older, at least to any extent sufficient to justify the huge price disparity between Lexapro and generic Celexa.
- (c) Forest was improperly promoting and marketing Celexa and Lexapro for an off-label use, *i.e.*, treating depression in children/adolescents under the age of 18, which was artificially boosting the sales of Celexa and making the introductory prescriptions for and sales of Lexapro appear more successful than they would have been absent this improper off-label promotion and marketing.
- (d) Forest was improperly promoting and marketing Memantine/Namenda for an off-label use, *i.e.*, treatment of mild to moderate Alzheimer's disease, which was artificially boosting the initial prescriptions for and sales of Memantine/Namenda, making the introduction of that product appear more successful than it really was.
- (e) Forest knew it would not be able to submit an sNDA for Memantine/Namenda to the FDA to treat mild to moderate Alzheimer's disease by mid-04 as represented, because Forest had two negative studies showing Memantine/Namenda was not efficacious for mild to moderate Alzheimer's disease and the positive data in Forest's possession did not indicate sufficient efficacy for the drug for that use to obtain FDA approval for

Memantine/Namenda in treating mild to moderate Alzheimer's disease, in light of those negative studies.

(f) Forest did not promptly release clinical studies or tests on its drugs, but rather, concealed and did not release or publicize negative studies on Celexa/Lexapro, while going to great lengths to release and publicize favorable Celexa/Lexapro studies that were contradicted by the concealed studies.

(g) Forest knew from internal data, as well as other materials available to it, that the drugs Celexa/Lexapro were associated with increased suicidality in all user populations, *i.e.*, children, adolescents and adults, but concealed this information while promoting and marketing those drugs to those populations and representing them to be well-tolerated in those populations.

(h) Forest's reported successful financial results were due, in material part, to Forest's promotion and marketing of Lexapro/Celexa for childhood/adolescent use and Memantine/Namenda for mild/moderate Alzheimer's disease and physicians prescribing those drugs for those off-label uses.

(i) The positive physician response Forest reported it was seeing in connection with the introduction of Lexapro was due, in part, to Forest promoting and marketing the drug for off-label childhood and adolescent use and physicians prescribing it for that use.

(j) Forest did not "scrupulously inform physicians about [its] products" or "communicat[e]" with them in "accurate . . . ways that . . . serve their patients' interests," as it was promoting and marketing Celexa/Lexapro for childhood/adolescent off-label use based on studies it publicized and/or distributed showing well-tolerated efficacy in that population, while

concealing other studies showing the drugs did not work in those populations and caused increased suicidality.

(k) The fact that Lexapro/Celexa in combination commanded the highest percentage of new SSRI prescriptions as Forest represented was not an “achievement attributable first and foremost to the virtues of the products,” as defendants stated, but rather was due in substantial part to Forest improperly promoting and marketing those drugs for the treatment of childhood and adolescent depression and the false claim that Lexapro “had a greater beneficial effect” than Celexa in treating depression.

(l) To the extent Forest had compared Lexapro to Celexa for treating depression, it found that Lexapro had no materially greater beneficial effect in treating depression, but concealed this from both the physician-prescribing community and the investment community.

(m) Forest’s “message” was not, as defendants stated, “correct based on carefully controlled experiments,” making “Lexapro . . . so successful”; Forest had manipulated its Celexa/Lexapro studies, publicizing ones that showed well-tolerated success with children and adolescents, while concealing other studies (larger and better) that showed no efficacy and increased suicidality.

(n) Forest was not only positioning Lexapro with physicians as the SSRI of choice for new patients, non-responsive patients and patients suffering recurrent episodes of depression, but also for the initial treatment of children and adolescents suffering from depression.

(o) One of the reasons the Lexapro launch was going “exceptionally well” and Celexa was continuing to sell well, and thus the two drugs were, in combination, gaining market

share was due to Forest's success in getting physicians to prescribe these drugs for off-label treatment of childhood and adolescent depression.

34. The chart below shows the price action of Forest stock during the relevant period and the events occurring relevant to the Company during that time frame:

JURISDICTION AND VENUE

35. The claims asserted arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 (“1934 Act”) and Rule 10b-5. Jurisdiction is conferred by §27 of the 1934 Act. Venue is proper pursuant to §27 of the 1934 Act. Forest is headquartered in New York City, false statements were made here and acts giving rise to the violations complained of occurred here.

THE PARTIES

36. (a) Plaintiff Pace Industry Union – Management Pension Fund, purchased the stock of Forest at artificially inflated prices during the Class Period and has suffered damages of \$862,876, as shown in the attached certification.

(b) Plaintiff Teamsters Affiliates Pension Plan purchased the stock of Forest at artificially inflated prices during the Class Period and has suffered damages of \$379,435, as shown in the attached certification.

(c) Plaintiff UNITE H.E.R.E. Staff Retirement Fund purchased the stock of Forest at artificially inflated prices during the Class Period and has suffered damages of \$247,395, as shown in the attached certification.

37. Defendant Forest has its executive offices in New York, New York. On 12/12/02, Forest announced that its stock had begun trading on the New York Stock Exchange. The stock had previously traded on the American Stock Exchange. Both these markets are “efficient” markets.

38. (a) Defendant Howard Solomon (“Solomon”) was Chairman and CEO of Forest during all relevant times. During the Class Period, defendant Solomon sold 3,800,000 shares of his Forest stock, 37% of the shares he actually owned, for \$221 million in insider trading proceeds.

(b) Defendant John E. Eggers (“Eggers”) was Vice President-Finance and Chief Financial Officer of Forest during all relevant times. During the Class Period, defendant Eggers sold 70,968 shares of his Forest stock, 59% of the shares he actually owned, for \$4.3 million in insider trading proceeds.

(c) Defendant Kenneth E. Goodman (“Goodman”) was President and Chief Operating Officer of Forest during all relevant times. During the Class Period, defendant Goodman sold 500,000 shares of his Forest stock, 11.2% of the shares he actually owned, for \$24.7 million in insider trading proceeds.

(d) Defendant Elaine Hochberg (“Hochberg”) was Senior Vice President-Marketing of Forest during all relevant times. During the Class Period, defendant Hochberg sold 223,456 shares of her Forest stock, 73% of the shares she actually owned, for \$12.4 million in insider trading proceeds.

(e) Defendant Lawrence S. Olanoff (“Olanoff”) was Executive Vice President-Scientific Affairs of Forest during all relevant times. During the Class Period, defendant Olanoff sold 337,256 shares of his Forest stock, 69% of the shares he actually owned, for \$23.5 million in insider trading proceeds.

(f) Defendant Mary E. Prehn (“Prehn”) was Vice President-Licensing and Corporate Development of Forest during all relevant times. During the Class Period, defendant Prehn sold 75,600 shares of her Forest stock, 88% of the shares she actually owned, for \$4.3 million in insider trading proceeds.

(g) Defendant Raymond Stafford (“Stafford”) was Executive Vice President-Global Marketing of Forest during all relevant times. During the Class Period, defendant

Stafford sold 155,000 shares of his Forest stock, 50% of the shares he actually owned, for \$9.3 million in insider trading proceeds.

(h) Defendant Charles E. Triano (“Triano”) was Vice President-Investor Relations of Forest during all relevant times. During the Class Period, defendant Triano sold 20,000 shares of his Forest stock, 100% of the shares he actually owned, for \$1.49 million in insider trading proceeds.

SCIENTER AND SCHEME ALLEGATIONS

39. During the Class Period, the defendants had both the motive and opportunity to conduct fraud. They also had actual knowledge of the falsity of the statements they made or acted in reckless disregard of the truth or falsity of those statements. In so doing, the defendants participated in a scheme to defraud and committed acts, practices and participated in a course of business that operated as a fraud or deceit on purchasers of Forest stock during the Class Period.

40. The Individual Defendants were Forest’s eight top executive officers charged with not only developing Forest’s business strategy, but also overseeing the implementation and execution of that strategy during the Class Period. Due to the circumstances described in this Complaint, nothing was more important to them than conceiving and then successfully implementing and executing a new business strategy/model, as their jobs and millions of dollars of bonuses and other benefits depended on their doing so, as, if they could do so, they stood to pocket millions and millions of dollars in salaries, bonus payments and stock option profits. If they did not, they knew their positions of power, prestige and profit at Forest would be in jeopardy.

41. Forest knew that in Copenhagen before it began to market Lexapro, the Danish Medicines Agency (“DMA”) said that Lundbeck’s second generation anti-depressant drug, Cipralex (Lexapro), had no clear advantages to its top-selling predecessor Cipramil (Celexa).

42. As stated in a *Reuters* article in January 2004:

Denmark's pharmaceutical firm H. Lundbeck's new anti-depressant Cipralex is not superior enough to its predecessor Cipramil to justify higher prices, scientists said. Lundbeck is pinning much of its future income to Cipralex succeeding its original blockbuster Cipramil which lost its European patent in 2002 and now faces cheap generic competition.

Declaring its new generation drug is more efficient than the old version, Lundbeck hopes to swap patients to the new pill while charging more for it.

A Swedish and an Australian scientists [sic] concluded in a study published in [2004's] first edition of the medical journal *Psychotherapy and Psychosomatics* that Lundbeck's statements are unfounded.

* * *

Cipramil accounts for around 80% of Lundbeck's total sales. In the US, where Cipramil is sold as Celexa, the patent expires in 2004.

* * *

Cipralex is retailed in the United States by Lundbeck's partner, Forest Labs under the name Lexapro.

43. On a quarterly basis, Forest held regional plan-of-action (POA) meetings for sales reps, and held nationwide meetings on an annual basis, normally in October, in Florida. Regional POA meetings lasted for approximately two to three days each quarter. Training for these meetings was conducted by sales executives and/or either a product manager or an assistant product manager from Forest's New York headquarters.

44. At the annual sales meetings in Orlando – lasting a week – COO/defendant Goodman and CEO/defendant Howard Solomon attended with the entire team of nationwide sales reps. Goodman and Solomon spoke to the team and provided an overview of the sales training focus. The theme was sometimes conveyed by showing slides with pictures of an internist or a child psychiatrist and then commenting that the internist is still writing too many prescriptions for Zoloft or the child psychiatrist is not writing enough prescriptions for Celexa or

Lexapro. Sales reps then separated into groups of 40 or so in order to begin the training portion of the meeting.

45. The sales reps received sales training at the meetings, which were in-line with corporate objectives. Each quarter, the POA meetings, as well as the annual meetings, focused on a specific message to ***promote*** their products. For instance, the goal for the quarter would be to market Lexapro to doctors for anxiety, panic or pediatric depression, which were also off-label indications. The quarterly focus or marketing message was oftentimes for off-label usage. If the focus involved pediatric depression (sales reps were commonly instructed to market Celexa and Lexapro for use in children), then the sales reps were instructed on how to overcome potential doctor concerns or questions. These “scripts” were presented by the sales reps through role-playing. The role-playing taught sales reps how to “get around” the fact that Celexa and Lexapro were not approved for certain indications by proactively addressing the topic, *i.e.*, off-label use.

46. Sales reps were given a script for informing doctors that Celexa and Lexapro were safe for children and adolescents, which consisted of the following approach: “Zoloft [which was approved for use in children] is an SSRI and Celexa/Lexapro are SSRIs, how different can they be? Pfizer is a large company with time and money to devote to studies to show the efficacy and safety for children, but you can rest assured that Celexa/Lexapro are both also safe for children.” The sales rep would actually provide the doctor with a copy of the study conducted by Pfizer on Zoloft with specific paragraphs pre-highlighted. The representations about the safety of Celexa/Lexapro for children and the study were proactively provided to doctors by Forest sales reps; sales reps were not supposed to wait for inquiries from the doctors but expected to provide these explanations up-front. In addition, managers would sometimes

accompany sales reps on visits and it was expected that the sales rep would follow the “script” taught in the training meetings.

47. Forest sales reps were commonly provided with copies and instructed to distribute journal articles for studies conducted by other companies for drugs in the same class, such as other SSRIs, for promotion of Celexa/Lexapro. As described above, the subject of the studies conducted by other companies were for indications that had *not* been approved by the FDA for Forest’s product. In addition, sales reps were specifically instructed to highlight certain paragraphs of the studies, and not to highlight others, as part of the sales training. Thus, Forest reps distributed articles for competitor products, endeavored to convince doctors that the findings applied to Forest’s products, and that it was unnecessary to waste money conducting the same study. The practice of taking credit for other studies was called “piggy-backing.” Forest reps were also sent to the offices of child psychologists, despite the fact that neither Celexa or Lexapro were approved for use in children.

48. The effort to promote Lexapro over Celexa when Celexa’s patent was about to expire was also intense. Sales reps were instructed to use the phrase, “Lexapro is Celexa on steroids” to illustrate the increased efficacy of Lexapro. In addition, sales reps informed doctors that studies showed Lexapro took effect after one to two weeks, whereas the other SSRIs (including Celexa) took effect within four to six weeks. After Lexapro was launched, sales reps told doctors who prescribed Celexa, including those prescribing to children, that if they felt comfortable with Celexa, they should feel comfortable with Lexapro.

PRE-CLASS PERIOD EVENTS AND STATEMENTS

49. Celexa, Forest’s flagship drug, which provided 70%-80% of Forest’s revenues and profits, had an exclusive marketing period which allowed Forest to charge very high and very profitable prices for the drug, originally to last until 9/03, after which generic Celexa would

flood the market causing prices for the drug to plunge. Forest's business strategy was to work with its licensor Lundbeck to develop a follow-on patented drug – Lexapro – which contained the same active ingredient as Celexa and therefore would be essentially the same as Celexa, but with sufficient claimed differences to justify the follow-on drug being granted a patent and its own period of marketing exclusivity extending for several years beyond Celexa "going generic," and to allow Forest to credibly claim the new Lexapro drug was superior in treating depression so as to justify physicians continuing to prescribe it to patients at much higher prices compared to generic Celexa. Once Lexapro was approved for sale by the FDA, Forest would stop promoting Celexa and have its salesforce, *i.e.*, "detail men," work on physicians to cause them to switch their patients receiving Celexa to the new drug – Lexapro – so that after Celexa "went generic" and prices for it plunged, Forest could continue to charge very high and profitable prices for what was essentially the same drug – Lexapro – for several more years, during Lexapro's five-year exclusive marketing period.

50. In order for this key product transition strategy to succeed, it was necessary that Celexa's exclusive marketing period last as long as possible so that when Forest was permitted by the FDA to begin to actively market Lexapro, Forest's salesforce would have many months to get physicians to transition their Celexa patients to Lexapro. In 3/01, Forest filed with the FDA for permission to market Lexapro for adults aged 18 years or older. By the Spring of 02, Forest's efforts to receive FDA approval for Lexapro had reached the point where Forest anticipated it would receive approval to market Lexapro in 8/02-9/02.

51. During 01, in order to attempt to extend Celexa's exclusive marketing period by six months, Forest exploited a provision in applicable law that permitted it to obtain an automatic six-month extension of Celexa's exclusive marketing period if it performed studies on the use of

Celexa in pediatric care by cooperating with its licensor, Lundbeck, and funding the studies so it could influence their outcome, keep track of their progress and control the public release and publicity concerning these studies. At that time, only one anti-depressant drug (Prozac) had been approved for prescription to adolescents – a gigantic market, which, if Forest could market either Celexa or Lexapro for, would vastly increase the size of the market for those drugs and the revenues and profits that Forest could obtain from them.

52. By late 01, Forest had completed a pediatric study on Celexa which showed the drug improved depression in children/adolescents and wanted to publicize the study so that its salesforce could use it to use to illegally market Celexa and Lexapro upon its upcoming introduction for off-label use for patients under 18 years of age. Thus, Forest arranged for this study to be presented publicly, publicizing it by way of a 12/13/01 Forest press release, stating:

Results of Escitalopram and Celexa™ Studies Presented at Major Scientific Conference

Forest Laboratories, Inc. announced that clinical study results were presented today at an annual meeting of neuropsychopharmacologists, including . . . a pooled analysis of flexible-dose studies demonstrating that patients with major depressive disorder treated with either escitalopram or Celexa™ (citalopram HBr) showed significantly greater improvement than patients receiving placebo, *and a study demonstrating that Celexa may significantly reduce depression in adolescents and children.*

* * *

“Forest is committed to the development of effective medications for the treatment of depression, and the results of these studies are especially encouraging,” said Howard Solomon, chairman and chief executive officer, Forest Laboratories.

* * *

Celexa in the Treatment of Pediatric Depression

Celexa was shown to reduce symptoms of depression in adolescents and children with major depressive disorder to a significantly greater extent than placebo in a randomized, double-blind, placebo-controlled, flexible-dose study of

174 pediatric patients (83 children and 91 adolescents). . . . The study also showed that Celexa was well tolerated. . . .

“This study is significant because few studies involving any antidepressant have shown efficacy compared to placebo in the treatment of depression in children and adolescents,” said Karen Dineen Wagner, MD, PhD, Department of Psychiatry and Behavioral Sciences, University of Texas Medical Branch at Galveston, and the study’s lead author. ***“Citalopram is now one of the few therapies for which we have data showing safety and efficacy for this population.”***

53. On 1/14/02, after Forest reported its 3rdQ F03 results, *Dow Jones News Service* reported:

Forest Labs Oper Chief: Lexapro Better Than Celexa

* * *

Escitalopram, which Forest has filed to brand-name Lexapro, has “***greater effect***, faster speed of action and fewer side effects” than Celexa, Goodman said.

* * *

Forest filed a new drug application with the Food and Drug Administration for Lexapro last March and expects an approvable letter from the agency by the end of January. ***“We should be in a position to receive approval and launch by the middle of this year,”*** Goodman said.

54. On 1/15/02, after Forest reported its 3rdQ F03 results, *Reuters* reported:

Forest Laboratories Inc. said on Tuesday fiscal third-quarter profits rose about 33 percent, beating Wall Street estimates, ***driven by strong demand for its flagship antidepressant, Celexa.***

* * *

The company hopes to leverage robust Celexa sales into developing its solid pipeline of experimental drugs, led by escitalopram [Lexapro], an antidepressant intended to succeed Celexa, and Memantine to treat Alzheimer’s disease.

55. On 4/2/02, Deutsche Bank issued a report “Initiating Coverage” on Forest after discussions with Goodman and Eggers. It stated:

** Forest has clearly established itself as the leading worldwide specialty pharmaceutical company both in terms of product sales and market cap, driven by the success of its antidepressant Celexa.

** The company now stands on the cusp of its next major growth driver, ***the next generation antidepressant Lexapro . . .***

* * *

Lexapro – Improved Celexa a Major and Visible Near-Term Growth Driver

Licensed from Lundbeck for the U.S. market in 1997, Lexapro (escitalopram) is the single-isomer of Celexa for the treatment of depression. . . . [W]e anticipate market launch by mid-2002, ***which should enable Forest to convert the vast majority of its existing Celexa franchise to Lexapro (which is patent-protected through at least 2009) by early 2005, when the first generics to Celexa could potentially reach the marketplace.*** Currently, Celexa is protected from generic competition by a five-year marketing exclusivity prior under the Waxman-Hatch Act that prohibits abbreviated new drug application (ANDA) filings until the expiration of the exclusivity period (which should occur in January 2004, ***including a six-month pediatric extension***).

56. On 4/24/02, Forest held a conference call for Forest shareholders, analysts, money managers and the financial media. During the call, the following transpired:

[Goodman:] . . . In Alzheimer’s, we are currently conducting three trials, all of which are enrolling on schedule. In moderate to severe Alzheimer’s [and] ***mild to moderate Alzheimer’s . . .***

* * *

The Lexapro launch is already being supported by pre-launch activities. That level of spend will ramp up as we embark on a national roll out, anticipated around mid-year, but as we have said previously, we plan to discontinue promotion and sampling behind Celexa at the commencement of the national Lexapro launch.

* * *

[Caller:] . . . ***[D]o you ever plan to conduct and present a prospective study comparing Lexapro and Celexa . . . to show superiority or is that not necessary?***

[Goodman:] . . . ***I believe it is not necessary.***

57. To condition the physician prescribing community for the upcoming introduction of Lexapro, Forest arranged for the pediatric Celexa study to be publicly presented again, this time at the Annual Meeting of the American Psychiatric Association in Philadelphia during 5/18-23/02. The study was entitled “A Randomized Placebo-Controlled Trial of Citalopram [Celexa] for the Treatment of Major Depression in Children and Adolescents.” The study, of 83 children aged 7-11 and 91 adolescents aged 12-17, stated:

Conclusions: In this population of children and adolescents, treatment with citalopram reduced depressive symptoms to a significantly greater extent than placebo treatment and was well tolerated.

* * *

Citalopram, an SSRI shown to be effective in the treatment of depression in the adult population, *appears well suited for use in children and adolescents because it has a favorable side effect profile, a low potential for drug-drug interactions, and is relatively safe in overdose, which is of concern in this population.*

(Footnotes omitted.) This study then gratuitously observed:

It is tempting to speculate that similar clinical results would be achieved in children and adolescents treated with the recently developed single isomer compound escitalopram [Lexapro], since the serotonin reuptake activity of citalopram is attributable to its S-isomer.

(Footnote omitted.) Thus, the study concluded:

[C]italopram treatment significantly improved depressive symptoms compared with placebo within 1 week in this population of children and adolescents. No serious adverse events were reported . . . These findings further support the use of citalopram in children and adolescents suffering from major depression.

58. On 7/17/02, Forest issued a release regarding the extension of Celexa’s exclusive marketing period due to a pediatric study it had performed on the drug:

Forest Receives Six-Month Extension on Celexa™ After FDA Review of Pediatric Data

. . . Forest Laboratories, Inc. announced today that the U.S. Food and Drug Administration (FDA) has granted a six-month extension on the marketing

exclusivity of Celexa™ (citalopram HBr). During this time, no application for a generic version of Celexa will be accepted by the FDA. The earliest a generic application could be submitted would be January 2004 after which point the application would undergo a review process by the FDA.

* * *

Currently, there are no therapies approved for the treatment of major depressive disorder in the pediatric population . . . – or 3.4 million children and adolescents under the age of 18

Given Forest's previous publicity concerning this study in 12/01 and 5/02, it was obvious that this study demonstrated that Celexa had been successful and well-tolerated in children and adolescents.

CLASS PERIOD STATEMENTS AND EVENTS

59. As of the outset of the Class Period, the pre-class period statements pleaded in the Pre-Class Period Events and Statements section above were alive, in the market and artificially inflating the market trading price of Forest's stock.

60. On 8/15/02, Forest issued a release announcing it had received FDA approval to market Lexapro for depression. It stated:

Lexapro™, the Single-Isomer of Celexa™, Receives FDA Approval for the Treatment of Major Depression

. . . Forest Laboratories, Inc. announced today that Lexapro™ (escitalopram oxalate), a powerful, effective and well-tolerated selective serotonin reuptake inhibitor (SSRI), has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of major depressive disorder. Forest expects Lexapro to be available in pharmacies by September 5th.

61. Forest was set to launch Lexapro on 9/5/02. To further publicize the supposedly successful Celexa/Lexapro pediatric care study, just before the Lexapro product launch and to condition the physician-prescribing community and impress investors and analysts, Forest arranged for the 9/1/02 edition of *Pediatric News* to contain an article on Celexa and its success in treating depression in children/adolescents which stated:

Celexa in Kids

Forest Laboratories Inc. was granted a 6-month extension on its market exclusivity for the selective serotonin reuptake inhibitor Celexa (citalopram hydrobromide), *after demonstrating its efficacy against symptoms of major depression in 83 children aged 7-11 years and 91 adolescents aged 12-17 years. . . . Celexa was well tolerated, Dr. Karen Wagner of the University of Texas, Galveston, reported at a neuropsychopharmacology meeting.*

62. As part of the formal marketing launch of Lexapro, on 9/5/02, Goodman appeared on CNNfn's "Street Sweep" for an interview:

ALI VELSHI, CNNfn ANCHOR, STREET SWEEP: Forest Labs is betting on a new drug to help boost its bottom line. Beginning today Lexapro is available to help treat depression. Forest Labs has been increasing revenue at a rate of at least 30 percent over the past year. . . . For more on Forest Labs, I'm joined by the company's president Ken Goodman.

* * *

VELSHI: I hate to be cynical, but is this one of those moves that we're seeing more and more from pharmaceutical companies to sort of change the make up of drugs a little bit so that it defacto extends your patent protection by getting a new patent on a slightly different drug?

GOODMAN: *No, actually, this is quite different . . . So, for patients we will have a drug that is more efficacious, acts more quickly, has lower side effects and has less drug interaction than the previous drug did.*

63. On 9/12/02, Deutsche Bank issued a report on Forest after meeting with Goodman and Eggers, who knew what they told Deutsche Bank would be reported to the investment community. Reporting and repeating what Forest's executives had said to them, Deutsche Bank's report stated:

Management Meetings Confirm Robust Outlook Supported by Multiple Growth Drivers

* * *

- Earlier this week, we sponsored two days of investor meetings with Forest Labs, which has bolstered our confidence in the company's already solid near and longer-term business outlook.

* * *

Last Thursday, September 5, Forest launched Lexapro, marking the commencement of the company's campaign to convert Celexa patients to this new antidepressant prior to the emergence of generic competition

First, management indicated that the clear focus of its Lexapro marketing strategy is *to target both new patients and individuals who are either dissatisfied with or have failed to respond to current treatments*. On this front, Lexapro should likely benefit from a favorable side effect profile relative to the other selective serotonin reuptake inhibitors (SSRIs) as the patient drop out rate due to adverse events was not statistically significantly different from placebo for the 10 mg dose (data contained in label).

64. On 10/15/02, Forest reported its 2ndQ F03 results, *i.e.*, the quarter ended 9/30/02, via a release which stated:

Howard Solomon, Chairman and Chief Executive Officer of Forest, said: "In the recently completed quarter Forest's antidepressant franchise significantly increased through the continuing strength of Celexa, augmented in the quarter by the successful launch in September of Lexapro. Although it is still early in the launch of Lexapro, we have experienced positive physician response and a strong uptake in Lexapro prescription volume."

65. On 10/15/02, Forest held a conference call for Forest shareholders, analysts, money managers and the financial media, during which the following transpired:

[Goodman:] . . . [W]e are very encouraged by the uptake of Lexapro and the overall market share gains for our antidepressant franchise.

. . . We are positioning Lexapro with [physicians as] the SSRI of choice when prescribing for new patients, those patients who are not responding to or not tolerating other SSRIs, and patients who are returning to the market with a recurring episode of depression. . . .

. . . Let me remind everybody of the timing for generic competition to Celexa We have five years of Hatch-Waxman exclusivity, *plus an additional six months of exclusivity under the pediatric initiative*.

* * *

We are also generating additional clinical data in both mild-to-moderate and moderate-to-severe Alzheimer's disease

* * *

As far as the promotional guidelines, the – you know, the difference in the promotional guidelines are, from that [sic] Forest already had as its policies, are

not that significant with respect to the overall ability to spend money as much as they are with some of the changes in what we spend the money on.

66. In 12/02, Forest again arranged for publicity indicating that the active ingredient shared by Celexa and Lexapro was effective in treating depression in minors with minimal adverse side effects *in two separate studies*, a “*booster shot*” for marketing the drug as well as for Forest’s stock. Forest arranged for the publication of the following article concerning two studies it and its licensor, Lundbeck, had performed on children and adolescents in the 12/1/02 edition of *Clinical Psychiatry News*, which stated:

Citalopram may help children’s depression. (Minimal Side Effects).

. . . Citalopram may improve symptoms of major depressive disorder with minimal side effects in children and adolescents, according to two studies presented at the Congress of the Collegium Internationale Neuro-Psycho-pharmacologicum.

The antidepressant was effective and well tolerated in a double-blind, placebo-controlled, flexible-dose study of 83 children and 91 adolescents, said Dr. Karen Wagner of the University of Texas, Galveston. Similar results were obtained in a retrospective study of 76 South African children and adolescents that considered the safety and efficacy of the drug relative to other selective serotonin reuptake inhibitor antidepressants. . . .

The studies are among the first to consider the safety and efficacy of antidepressant agents in children, noted Dr. Duncan Rodseth of Lundbeck.

The 8-week Texas trial compared 20-40 mg of citalopram with placebo in children and adolescents aged 7-17 years with major depressive disorder who had exhibited symptoms for at least 4 weeks prior to enrollment.

* * *

In the South African study investigators reviewed data on 76 children and adolescents being treated with citalopram for an average of 102 days at doses ranging from 5 to 30 mg, Dr. Rodseth said. *Minimal adverse effects were observed, he said.*

67. The statements made by Forest or on behalf of Forest between 8/02-12/02 were false and misleading when made in their own right and for failing to disclose the following adverse facts necessary to make the statements made not misleading:

- (a) Forest was aware of a large multi-year study of Celexa for treating childhood/adolescent depression performed by Lundbeck with Forest's knowledge, consent and input, which showed that Celexa was not efficacious in that population and produced increased suicidality.
- (b) Lexapro was not superior to or more efficacious than Celexa in treating depression in adults 18 years or older, at least to any extent sufficient to justify the huge price disparity between Lexapro and generic Celexa.
- (c) Forest was improperly promoting and marketing Celexa and Lexapro for an off-label use, *i.e.*, treating depression in children/adolescents under the age of 18, which was artificially boosting the sales of Celexa and making the introductory prescriptions for and sales of Lexapro appear more successful than they would have been absent this improper off-label promotion and marketing.
- (d) Forest did not promptly release clinical studies or tests on its drugs, but rather, concealed and did not release or publicize negative studies on Celexa/Lexapro, while going to great lengths to release and publicize favorable Celexa/Lexapro studies that were contradicted by the concealed studies.
- (e) Forest knew from internal data, as well as other materials available to it, that the drugs Celexa/Lexapro were associated with increased suicidality in all user populations, *i.e.*, children, adolescents and adults, but concealed this information while promoting and

marketing those drugs to those populations and representing them to be well-tolerated in those populations.

(f) Forest's reported successful financial results were due, in material part, to Forest's promotion and marketing of Lexapro and Celexa for childhood/adolescent use and physicians prescribing the drugs for those off-label uses.

(g) The positive physician response Forest reported it was seeing in connection with the introduction of Lexapro was due, in part, to Forest promoting and marketing the drug for childhood and adolescent use and physicians prescribing it for that use.

(h) To the extent Forest had compared Lexapro to Celexa for treating depression, it found that Lexapro had no materially greater beneficial effect in treating depression, but concealed this from both the physician-prescribing community and the investment community.

(i) Forest was not only positioning Lexapro with physicians as the SSRI of choice for new patients, non-responsive patients and patients suffering recurrent episodes of depression, but also for the initial treatment of children and adolescents suffering from depression.

68. On 1/16/03, Forest held a conference call for Forest's shareholders, analysts, money managers and the financial media, during which the following transpired:

[Triano:] . . . By way of a Safe Harbor statement . . . various remarks that we may make about future expectations, plans and prospects for the company constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, and actual results may be different. . . .

[Goodman:] We saw a dramatic expansion in our antidepressant franchise, with total franchise sales of \$4.52 million during the quarter. Of this, Lexapro contributed \$81 million in sales, while Celexa sales were \$371 million. *The Lexapro launch, now 4 months old, is going exceptionally well and we expect Lexapro to be one of the most successful launches in the industry. We have also been pleased with the performance of Celexa . . . Since the launch*

of Lexapro in September, our combined antidepressant franchise has gained nearly 4 market share points within the SSRI category. . . .

All of the competing products have lost share since the Lexapro launch. Lexapro has gained about an 8 percent market share based on new prescriptions, half coming from Celexa, and the balance in roughly equal proportions from new patients and patients switched from other therapies.

* * *

I want to remind [everybody again of] the timing for the generic competition for Celexa. . . . We have 5 years of Hatch-Waxman exclusivity, **[plus an additional] six months of exclusivity under the pediatric initiative.**

69. On 4/22/03, Forest reported its F03 results via a release stating:

Forest Laboratories, Inc., an international pharmaceutical manufacturer and marketer, today reported record revenues and earnings for its fiscal fourth quarter and twelve months ended March 31, 2003.

* * *

Howard Solomon, Chairman and Chief Executive Officer of Forest, said: ***"Our significant growth in earnings this past fiscal year was based principally on increased sales of our highly successful antidepressant products – Celexa and Lexapro. Those products currently account for a higher and growing percentage of new prescriptions for SSRIs than any other products in the category.***

70. On 5/28/03, Forest President and COO Goodman spoke at the Freeman Billings Technology & Growth Investor Conference. He stated:

[B]y way of a Safe Harbor statement . . . various remarks that we may make about future expectations, plans or prospects for the company constitute forward-looking statements, and actual results may be different.

I know most of you are up to speed on our outlook for the coming year as we had discussed it recently on our end of year conference call. But I think we will just quickly go through and distill some of next year's activities and what our plans are for the year.

* * *

Let us talk about Lexapro. I think at this point it is apparent that Lexapro has been and continues to be a very successful product launch. Its performance continues at or above our expectations. ***We anticipate that the advent of new comparative clinical data and additional indications will serve to sustain if not***

accelerate its growth rate in the SSRI market. It is our belief that Lexapro has the clinical differentiation and meaningful selling points to physicians that will enable it to become the leading market share product in the category. The level of new prescriptions continues to grow as physicians are prescribing Lexapro.

More and more physicians are coming onboard all the time and gaining experience with the product

71. The statements made by Forest or on behalf of Forest between 1/03-5/03 were false and misleading when made in their own right and for failing to disclose the following adverse facts necessary to make the statements made not misleading:

- (a) Forest was aware of a large multi-year study of Celexa for treating childhood/adolescent depression performed by Lundbeck with Forest's knowledge, consent and input, which showed that Celexa was not efficacious in that population and produced increased suicidality.
- (b) Lexapro was not superior to or more efficacious than Celexa in treating depression in adults 18 years or older, at least to any extent sufficient to justify the huge price disparity between Lexapro and generic Celexa.
- (c) Forest was improperly promoting and marketing Celexa and Lexapro for an off-label use, *i.e.*, treating depression in children/adolescents under the age of 18, which was artificially boosting the sales of Celexa and making the introductory prescriptions for and sales of Lexapro appear more successful than they would have been absent this improper off-label promotion and marketing.
- (d) Forest did not promptly release clinical studies or tests on its drugs, but rather, concealed and did not release or publicize negative studies on Celexa/Lexapro, while going to great lengths to release and publicize favorable Celexa/Lexapro studies that were contradicted by the concealed studies.

(e) Forest knew from internal data, as well as other materials available to it, that the drugs Celexa/Lexapro were associated with increased suicidality in all user populations, *i.e.*, children, adolescents and adults, but concealed this information while promoting and marketing those drugs to those populations and representing them to be well-tolerated in those populations.

(f) Forest's reported successful financial results for Celexa/Lexapro were due, in material part, to Forest's promotion and marketing of Lexapro and Celexa for childhood/adolescent use and physicians prescribing the drugs for those off-label uses.

(g) The positive physician response Forest reported it was seeing in connection with the introduction of Lexapro was due, in part, to Forest promoting and marketing the drug for childhood and adolescent use and physicians prescribing it for that use.

(h) To the extent Forest had compared Lexapro to Celexa for treating depression, it found that Lexapro had no materially greater beneficial effect in treating depression, but concealed this from both the physician-prescribing community and the investment community.

(i) Forest was not only positioning Lexapro with physicians as the SSRI of choice for new patients, non-responsive patients and patients suffering recurrent episodes of depression, but also for the initial treatment of children and adolescents suffering from depression.

(j) One of the reasons the Lexapro launch was going exceptionally well and Celexa was continuing to sell well, and thus the two drugs were, in combination, gaining market share, was Forest's success in getting physicians to prescribe these drugs for off-label treatment of childhood and adolescent depression.

72. As Forest received its six-month Celexa exclusive marketing extension, publicized the success of Celexa and Lexapro in treating pediatric depression without major adverse side effects, was successfully introducing Lexapro, getting physicians to transition patients from Celexa to Lexapro based on claims of superior efficacy in treating depression, and anticipated FDA approval to market Memantine/Namenda for moderate to severe Alzheimer's based upon favorable results from a Memantine/Namenda study on mild/moderate Alzheimer's, its stock took off. Forest's stock, after closing at around \$33 on 7/11/02, climbed higher, reaching \$54 in late 11/02 and \$61.35 on 6/17/03. As Forest's stock soared higher, its top officers bailed out, selling some 2.27 million shares of Forest stock they owned, pocketing \$111 million in illegal insider trading proceeds.

73. However, from 6/03 to 8/03, a series of negative events unfolded which caused Forest's stock to decline sharply. The largest market for Forest's Alzheimer's disease drug would be in the *mild* category of Alzheimer's disease (45+% of cases). During 02 and 03, Forest told analysts it was conducting trials of Memantine/Namenda for mild Alzheimer's disease, expected favorable results and anticipated FDA approval of this expanded use of Memantine/Namenda. However, in 6/03, while Forest was actively seeking FDA approval for its Memantine/Namenda drug for moderate/severe Alzheimer's disease, Forest was forced to publish the results of the Memantine/ Namenda mild/moderate study it had repeatedly told analysts it was conducting and had to reveal that that study had failed to show any efficacy in treating mild/moderate Alzheimer's disease, a stunning disappointment to the investment community.

74. On 6/19/03, *Reuters* reported on the results of Forest's mild/moderate Alzheimer's study for Memantine/Namenda:

Alzheimer's drug did not improve cognition . . .

... Forest Laboratories Inc. said on Thursday a clinical trial of an experimental treatment did not significantly improve awareness and reasoning in patients with mild to moderate Alzheimer's disease.

The trial results, which could slash the potential market for the most important drug in Forest's pipeline, sent the company's shares tumbling 12 percent.

* * *

[I]f only moderate-to-severe patients are administered the drug, it would severely dent Forest's potential market.

"The hope was that if the data was really compelling, it could be used 'off-label' for mild-to-moderate patients," Lickrish [analyst at Punk, Ziegel & Co.] said.

About 4 million Americans have Alzheimer's disease, according to the Alzheimer's Association.

Recent data shows that moderate patients account for 38.5 percent of all afflicted, and severe patients comprise 16.5 percent, according to Deutsche Bank's Steinberg. *The remaining 45 percent are considered to have early forms of the disease.*

75. On 6/19/03, Piper Jaffray reported:

Memantine Fails Mild-to-Moderate Alzheimer's Trial Key Points

- This morning, Forest announced that a recently completed clinical trial analyzing the impact of memantine in mild-to-moderate Alzheimer's disease patients *failed to demonstrate statistical superiority* relative to the placebo arm.

* * *

- What is unfortunate here is that Forest had hoped to position memantine as the only agent approved for use in all Alzheimer's patients . . .
- . . . [T]he results offer a distinct counter-detailing point for competing sales reps to point out if memantine finally reaches the market. *As a result, the level of off-label usage is likely to be lower than previously*

believed unless a monotherapy trial, to be completed later this year, produces strong results in favor of memantine.

76. On 6/20/03, *Knight Ridder* reported:

Experimental Alzheimer's Drug Fails to Improve Patients' Lives

An experimental Alzheimer's drug failed to improve the daily lives of patients with mild to moderate cases of the brain disorder, Forest Labs said yesterday.

The news sent shares of Midtown-based Forest plunging \$7.32 to \$53.29.

* * *

"It's important. Forest is a one-drug company right now" with its antidepressant Celexa, said Michael Obuchowski, a portfolio manager at Ashland Management.

77. This caused Forest stock to plunge by more than \$8 per share from \$61.19 on 6/18/03 to \$52.85 on 6/19/03 – on exceptionally large volume of 14,523,300 shares – *the largest one-day stock drop in Forest's history as a public company!*

78. On 7/15/03, Forest reported its 1stQ F04 results via a press release. The release warned of slowing growth in overall SSRI prescription rates “perhaps due to overall economic conditions,” which might hurt Forest’s F04 EPS growth. However, the release also stated:

Howard Solomon, Chairman and Chief Executive Officer of Forest, said: “During the quarter our antidepressant franchise (Celexa and Lexapro) achieved the leading current market share of both new and total prescriptions for SSRIs. New prescriptions for Lexapro now exceed those of Celexa, and Lexapro’s market share increase more than offset the share decline for Celexa. *We look forward to a continuation of Lexapro’s strength in the market which has been driven by consistent physician and patient response to the clinical attributes of the product.*”

79. On 7/15/03, *Bloomberg* reported:

Forest Labs Says 2003 Profit May Lag; Shares Drop

Forest Laboratories Inc., the maker of the Celexa antidepressant, said profit this year may fall short of forecasts because of slowing growth for depression drugs. The company’s shares tumbled 9.4 percent.

* * *

“Maybe the fast growth in this company is done,” said Charles Ryan, an analyst for the BB&T Large Company Growth Fund, which holds 30,000 Forest shares. “It’s definitely a shock to me. This makes investors nervous.”

Even with today's drop, Forest shares have gained 40 percent in the past year. They dropped \$5.08 to \$49.25 as of 4 p.m. in New York Stock Exchange composite trading. **Today's drop wiped out almost all of the stock's gain in 2003.**

80. The disappointing development of the failed Memantine/Namenda mild/moderate trial, together with an apparent slowing of SSRI prescriptions in the summer of 03, caused Forest's stock price to fall to as low as \$41.85 on 8/20/03, wiping out most of the stock's large gains since the beginning of the Class Period on 8/15/02, when Forest had misleadingly caused small, short pediatric use Celexa/Lexapro studies to be publicized while concealing the much larger, longer and more comprehensive Lundbeck study which showed Celexa/Lexapro did not work on depressed children/adolescents **and** caused increased suicidality. **This sharp stock collapse showed Forest's executives that the investment community would not tolerate disappointing news regarding Lexapro or Memantine/Namenda.** As Forest's stock plunged lower, Forest's insiders stopped their insider selling, while undertaking renewed efforts to push the stock back up much higher.

81. In mid-7/03, Forest issued its F03 annual report. It contained a letter from Solomon, stating:

I wrote last year about integrity in business. . . . [T]here have been the most blatant, shameful frauds, so extreme it is astonishing that anyone could conceive them or expect them to survive. . . . A good cleanup is timely.

* * *

[T]he potency of and the necessity for our products, and the fact that patients (and the government that often pays the bill) have limited choices, does put a higher burden of responsibility on our industry than if we were selling confections. We are dealing with health and pain and profound human happiness, and not entertainment. **Marketing our products requires us to scrupulously inform physicians about those products. We are constantly communicating with**

physicians, but it must always be accurate and in ways that ultimately serve their patients' interests. Above all, it is incumbent on us not to abuse our access to physicians in ways that compromise their responsibility to their patients.

* * *

[O]ur successful results for the fiscal year that ended on March 31, 2003 . . . are largely based on our antidepressant franchise – Lexapro and Celexa – which together now command the highest percentage of new prescriptions in the SSRI category. *That is an achievement attributable first and foremost to the virtues of the products themselves. We had thought Celexa was the best of the SSRI's, but Lexapro, the S-enantiomer of Celexa, is even better.*

* * *

We compared Lexapro to Celexa and were delighted to find that it had a greater beneficial effect . . . And that is why Lexapro now accounts for over 50% of new prescriptions for our antidepressant products and over eleven percent of all new SSRI prescriptions only eight months after it was introduced. . . .

When we say Lexapro has advantages over other SSRI's, that means that for many patients it is less likely to have undesirable side effects, and it is more likely to offer greater effectiveness. That is not true for all patients because nothing is true for all patients but it is true for many patients. What that means is that for those patients for whom their current treatment is flawed, with undesirable side effects, for example, they are more likely to do better if switched to Lexapro. And for new patients the likelihood is that they will receive excellent results if they are started on Lexapro. *That is our message; it is correct based on carefully controlled experiments, and based on physician experience. And that is why Lexapro is so successful.*

82. The statements made by Forest or on behalf of Forest during 7/03 were false and misleading when made in their own right and for failing to disclose the following adverse facts necessary to make the statements made not misleading:

(a) Forest was aware of a large multi-year study of Celexa for treating childhood/adolescent depression performed by Lundbeck with Forest's knowledge, consent and input, which showed that Celexa was not efficacious in that population and produced increased suicidality.

(b) Lexapro was not superior to or more efficacious than Celexa in treating depression in adults 18 years or older, at least to any extent sufficient to justify the huge price disparity between Lexapro and generic Celexa.

(c) Forest was improperly promoting and marketing Celexa and Lexapro for an off-label use, *i.e.*, treating depression in children/adolescents under the age of 18, which was artificially boosting the sales of Celexa and making the introductory prescriptions for and sales of Lexapro appear more successful than they would have been absent this improper off-label promotion and marketing.

(d) Forest did not promptly release clinical studies or tests on its drugs, but rather, concealed and did not release or publicize negative studies on Celexa/Lexapro, while going to great lengths to release and publicize favorable Celexa/Lexapro studies that were contradicted by the concealed studies.

(e) Forest knew from internal data, as well as other materials available to it, that the drugs Celexa/Lexapro were associated with increased suicidality in all user populations, *i.e.*, children, adolescents and adults, but concealed this information while promoting and marketing those drugs to those populations and representing them to be well-tolerated in those populations.

(f) Forest's reported successful financial results for Celexa/Lexapro were due, in material part, to Forest's promotion and marketing of Lexapro/Celexa for childhood/adolescent use and physicians prescribing the drugs for those off-label uses.

(g) The positive physician response Forest reported it was seeing in connection with the introduction of Lexapro was due, in part, to Forest promoting and marketing the drug for childhood and adolescent use and physicians prescribing it for that use.

(h) Forest did not “scrupulously inform physicians about [its] products” or “communicat[e]” with them in “accurate . . . ways that . . . serve their patients’ interests,” as it was promoting and marketing Celexa and Lexapro for childhood/adolescent off-label use based on studies it publicized and/or distributed showing well-tolerated efficacy in that population, while concealing other studies showing the drugs did not work in those populations and caused increased suicidality.

(i) The fact that Lexapro and Celexa in combination commanded the highest percentage of new SSRI prescriptions as Forest represented was not an “achievement attributable first and foremost to the virtues of the products,” as defendants stated, but rather was due in substantial part to Forest improperly promoting and marketing these drugs for the treatment of childhood and adolescent depression and the false claims that Lexapro “had a greater beneficial effect” than Celexa in treating depression.

(j) To the extent Forest had compared Lexapro to Celexa for treating depression, it found that Lexapro had no materially greater beneficial effect in treating depression, but concealed this from both the physician-prescribing community and the investment community.

(k) Forest’s “message” was not, as defendants stated, “correct based on carefully controlled experiments,” thus making “Lexapro . . . so successful”; Forest had manipulated its Celexa/Lexapro studies, publicizing ones that showed well-tolerated success with children and adolescents, while concealing other studies (larger and better) that showed no efficacy and increased suicidality.

(l) Forest was not only positioning Lexapro with physicians as the SSRI of choice for new patients, non-responsive patients and patients suffering recurrent episodes of

depression, but also for the initial treatment of children and adolescents suffering from depression.

(m) One of the reasons the Lexapro launch was going exceptionally well and Celexa was continuing to sell well, and thus the two drugs were, in combination, gaining market share was due to Forest's success in getting physicians to prescribe these drugs for off-label treatment of childhood and adolescent depression.

83. In 8/03, Pfizer, the manufacturer of Zoloft, *the largest selling SSRI anti-depressant drug in the world*, publicized tests it had conducted which showed that Zoloft was effective with children and adolescents without increasing suicidality. Pfizer also indicated it would ask the FDA to allow it to include this "safety" information on the Zoloft label. Because of the widespread use of Zoloft, this announcement received widespread publicity. On 8/27/03, *The Wall Street Journal* reported:

Antidepressant Use for Kids Gains Support – New Research Shows Zoloft Eases Debilitating Symptoms; Judging the Suicide Risk

MANY PARENTS FACE this quandary: When kids are seriously depressed, are they better off on antidepressants or not?

Amid recent concerns that the drugs could increase the suicide risk for kids, parents may find some reassurance in an article in this week's Journal of the America Medical Association. *New research reported there showed that the antidepressant Zoloft was modestly more effective than a placebo at easing major depression in children and adolescents, while showing no increase in suicide attempts.*

* * *

Pfizer says it has received an FDA letter that likely will allow the company to add the pediatric-safety information from the trials to Zoloft's label, but it still has to work out the wording with the FDA.

84. On 9/24/03, Forest received FDA panel approval to market Memantine/Namenda for moderate to severe Alzheimer's. On 9/25/03, Morgan Stanley reported:

FDA Advisory Panel Gives Memantine the Nod

* * *

- **This is clearly positive news for FRX**

The FDA typically follows the panel's recommendation with respect to approving new drugs. Going into the meeting we were expecting a favorable outcome, but the market was more skeptical and was obviously waiting for a nod from the panel, as the stock jumped almost \$4 on the positive recommendation.

85. On 10/14/03, Forest held a conference call for investors and analysts during which the following transpired:

[Triano:] By way of a Safe Harbor Statement, let me add that various remarks that we may make about future expectations, plans and prospects for the company constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and actual results may be different.

* * *

[Goodman:] *We continue to be very encouraged by the strong physician and patient satisfaction levels with Lexapro . . .*

* * *

We expect to see results from additional studies for Namenda in mild to moderate Alzheimer's patients later this year. . . .

* * *

[David Larish – Analyst:] . . . [B]ased on the additional studies going on for the mild to moderate, you indicated that they would be completed by year-end. Do you anticipate when you might be in a position to release or discuss any of the results?

[Goodman:] *We always release results as soon as we get them. When there are any study [sic] that's material at Forest, we release results as soon as we can.*

* * *

[Corey Davis – Analyst:] Just back to the mild to moderate study [I]f it doesn't work in your favor, do you still have an obligation to publish it, and I guess how widely would you disseminate it if it actually isn't successful?

[Goodman:] *Well, I think from a scientific standpoint, we will disseminate it in a responsible way, and certainly we will disclose the top line results when we get them. And if it's not in our favor, it's not in our favor.*

86. On 12/8/03, Prudential Equity Group issued a report on Forest after meeting with Goodman and Eggers, who knew the information they gave Prudential would be repeated and reported to the market in Prudential's report, which stated:

We recently had the opportunity to meet with FRX's management and walked away feeling that things are tracking well at the company. The meeting lent support to our Overweight rating.

CELEXA/LEXAPRO: FLAGSHIP FRANCHISE POSITIONED FOR CONTINUED GROWTH. Both FRX and the investment community continue to focus of the conversion of older Celexa to newer Lexapro. There are currently three "levers" the company is pulling, or about to pull, to drive the continued conversion of the franchise ahead of Celexa generics showing up Whereas FRX's strategy for the depression franchise has formerly been to stress total franchise growth, that has evolved to focus more on growing Lexapro market share using a combination of changes to its pricing strategy, sales force promotional incentives, *and roll-out of new clinical research (comparing Lexapro to competitors; soon to launch new indications that will differentiate Lexapro from Celexa even further). The one issue that worries management the most is converting as much Celexa as possible before generics arrive. . . . The evolution of the conversion strategy is as follows:*

- Initial strategy – Overall franchise growth.
- Initiated conversion process in September-03 quarter. Efforts started with FRX incentivizing their sales force to favor Lexapro growth in addition to overall SSRI franchise growth. During the quarter FRX also introduced Lexapro head to head data versus competitor products.
- In the current December-03 quarter, reps are now being paid ONLY for Lexapro growth, and *new head to head data vs. Pfizer's . . . Zoloft*, as well as a new Celexa to Lexapro switching study, *are being rolled out for use in sales promotion.*

* * *

One of the components critical to Lexapro's rapid penetration has been FRX's ability to generate supportive data against their primary competitors. Near term comparative data highlighted at the meeting included:

- **New head to head comparison vs. Pfizer's Zoloft.** . . . As expected, this study demonstrated that patients are able to get the full Lexapro effect at the 10mg starting dose (*i.e.*, without the need for dose titration).

* * *

NAMENDA: EXCITEMENT BUILDING FOR LAUNCH OF THIS HEAVILY ANTICIPATED NEW DRUG FOR ALZHEIMER'S DISEASE. FRX should begin shipping Namenda to wholesalers within the next 2 weeks (orders expected to be "in house" by December 17th), with placement on pharmacy shelves by the last week of December or the first week of January.

87. On 12/9/03, Deutsche Bank issued a report on Forest after meeting with Goodman and Eggers. Its report reflected what Goodman and Eggers told them. It stated:

- We recently sponsored a number of investors meetings with the management of Forest, which confirmed a number of potential developments over the next several months to maintain a high level of interest in the shares.

* * *

We came away from these meetings with a sense that the outlook for Forest's business remains robust, with a number of potential developments over the next several months to maintain a high level of interest in the shares.

Specific events include the impending launch of the new Alzheimer's treatment Namenda, improved visibility and perhaps an acceleration in the ongoing switch from Celexa to Lexapro . . .

Namenda Launch Imminent – Sales Force Expansion Ahead of Plan

With respect to the upcoming launch for Namenda, which received final FDA approval just seven weeks ago for the treatment of moderate to severe Alzheimer's disease, Forest expects shipping to wholesalers to commence at the end of this month . . . with the drug being widely available in pharmacies by the second week of January.

* * *

Lexapro Rxs – Poised to Accelerate?

On the Celexa/Lexapro front, the company has already converted 64% of new prescriptions to Lexapro after 15 months of marketing. For the most recent

week, Lexapro held a 16% share of new prescriptions in the U.S. depression marketplace versus a 9% share for Celexa, according to data from IMS America. While Forest has primarily focused on expanding its share of the depression market with both Celexa and Lexapro since Lexapro's launch in September 2002, the company is now moving into the next phase of its marketing strategy with this approximate \$2.1 billion antidepressant franchise with the implementation of a more aggressive switch campaign.

* * *

The other development that should aid Forest's switch campaign are the results from the company's eight-week, 200-patient, switch study comparing Lexapro and Celexa, which the sales force has only recently been utilizing.

88. Pfizer's 8/03 announcement that Zoloft was effective in treating children and adolescents without adverse side effects was a very serious competitive blow to Forest, which was counting on increased off-label use of Celexa/Lexapro for childhood and adolescent depression to boost prescriptions of those drugs and Forest's sales and profits. In order to help market Lexapro in competition with Zoloft and continue to boost Lexapro prescriptions by physicians, on 12/10/03, Forest issued a release stating:

Starting Dose of Lexapro™ as Effective as Optimally Dosed Zoloft® in the Treatment of Major Depressive Disorder

... Forest Laboratories, Inc. announced today the results of a clinical study, which showed that Lexapro™ (escitalopram oxalate) is as effective and well tolerated as Zoloft® (sertraline hydrochloride). ... Both Lexapro and Zoloft belong to a class of antidepressants known as selective serotonin reuptake inhibitors (SSRIs).

The study was presented in Puerto Rico at an annual meeting of neuropsychopharmacologists.

* * *

Study Conclusions

Lexapro and Zoloft demonstrated comparable efficacy in reducing symptoms of depression and anxiety in patients with major depressive disorder. . . .

Both Lexapro and Zoloft were well tolerated

89. During the Fall of 03, Forest's stock price again began to move higher, as an FDA panel and then the FDA itself approved Memantine/Namenda for moderate/severe Alzheimer's disease and as Forest published the results of its study on 12/10/03 that *Lexapro was as effective as the SSRI drug Zoloft*, manufactured by Pfizer, after Pfizer's own Zoloft study represented it was beneficial to adolescents with no increased suicidal risk.

90. On 12/11/03, RBC Capital Markets issued a report on Forest, which stated:

Additional Head-To-Head Data For Lexapro

Event

Forest releases head-to-head trial results comparing Lexapro with Zoloft.

Investment Opinion

- **Positive Competitive Data.** Forest released results from an eight-week head-to-head clinical trial demonstrating that *Lexapro was as effective as Zoloft in relieving the symptoms of major depressive disorder while providing the benefit of a simpler dosing regimen*.
- **Results Provide Effective Competitive Positioning.** The trial results continue the modest but important shift in promotional strategy for the Forest sales team. Recall that Forest recently released head-to-head clinical data demonstrating that Lexapro was as effective as Effexor XR but better tolerated. *The release of the Zoloft head-to-head data is a continuation of this theme and provides another source of competitive information to aid the salesforce in effectively positioning Celexa versus its major competitors. The study is significant because Zoloft is currently the number one prescribed antidepressant in the US market.*

91. The statements made by Forest or on behalf of Forest between 10/03-12/03 were false and misleading when made in their own right and for failing to disclose the following adverse facts necessary to make the statements made not misleading:

- (a) Forest was aware of a large multi-year study of Celexa for treating childhood/adolescent depression performed by Lundbeck with Forest's knowledge, consent and

input, which showed that Celexa was not efficacious in that population and produced increased suicidality.

(b) Lexapro was not superior to or more efficacious than Celexa in treating depression in adults 18 years or older, at least to any extent sufficient to justify the huge price disparity between Lexapro and generic Celexa.

(c) Forest was improperly promoting and marketing Celexa and Lexapro for an off-label use, *i.e.*, treating depression in children/adolescents under the age of 18, which was artificially boosting the sales of Celexa and making the introductory prescriptions for and sales of Lexapro appear more successful than they would have been absent this improper off-label promotion and marketing.

(d) Forest did not promptly release clinical studies or tests on its drugs, but rather, concealed and did not release or publicize negative studies on Celexa/Lexapro, while going to great lengths to release and publicize favorable Celexa/Lexapro studies that were contradicted by the concealed studies.

(e) Forest knew from internal data, as well as other materials available to it, that the drugs Celexa/Lexapro were associated with increased suicidality in all user populations, *i.e.*, children, adolescents and adults, but concealed this information while promoting and marketing those drugs to those populations and representing them to be well-tolerated in those populations.

(f) Forest's reported successful financial results for Celexa/Lexapro were due, in material part, to Forest's promotion and marketing of Lexapro and Celexa for childhood/adolescent use and physicians prescribing the drugs for those off-label uses.

(g) The positive physician response Forest reported it was seeing in connection with the introduction of Lexapro was due, in part, to Forest promoting and marketing the drug for childhood and adolescent use and physicians prescribing it for that use.

(h) To the extent Forest had compared Lexapro to Celexa for treating depression, it found that Lexapro had no material greater beneficial effect in treating depression, but concealed this from both the physician-prescribing community and the investment community.

(i) Forest was not only positioning Lexapro with physicians as the SSRI of choice for new patients, non-responsive patients and patients suffering recurrent episodes of depression, but also for the initial treatment of children and adolescents suffering from depression.

(j) One of the reasons the Lexapro launch was going exceptionally well and Celexa was continuing to sell well, and thus the two drugs were, in combination, gaining market share was due to Forest's success in getting physicians to prescribe these drugs for off-label treatment of childhood and adolescent depression.

92. Based on the 9/24/03 FDA panel and 10/17/03 FDA approval of the sale of Memantine/Namenda for moderate/severe Alzheimer's disease, during 10/03-2/04, Forest began to manufacture Memantine/Namenda and stock drug wholesalers and pharmacies with the drug, while training its salesforce for Memantine/Namenda promotion, knowing that it would be permitted to begin to actively market, *i.e.*, detail, Memantine/Namenda on or about 3/1/04. Even though Forest could not legally market Namenda for mild to moderate Alzheimer's disease, in anticipation of the formal marketing launch of Memantine/Namenda and to help condition the physician-prescribing community to prescribe Namenda for "off label" mild to moderate use, on

1/7/04, Forest publicized a new study which indicated that Memantine/Namenda was efficacious for patients suffering from mild/moderate Alzheimer's disease, representing that this study would be sufficient to obtain FDA approval to market the drug for that purpose, assuring them that it could obtain FDA approval to market Memantine/Namenda for mild to moderate Alzheimer's disease based on one successful study alone. Forest told analysts and investors that, as a result of this successful study, it intended to file an sNDA with the FDA to approve the use of Memantine/Namenda for the treatment of mild/moderate Alzheimer's disease in mid-04. This study was important, coming after Forest had released the results of the disappointing "failed" Memantine/Namenda mild/moderate study on 6/19/03. As a result of this extraordinarily surprising positive news, Forest stock skyrocketed from \$61.50 on 1/6/04 to \$71.09 on 1/7/04, on huge volume of 9.9 million shares – ***Forest stock's largest one-day price increase in history*** – as this new information indicated that Memantine/Namenda would, after all, end up being available for prescription to the entire spectrum of Alzheimer's disease patients – mild, moderate and severe – a gigantic market – giving the drug a multi-billion dollar potential.

93. On 1/7/04, Forest issued a press release regarding Namenda, stressing that Forest's test showed the drug worked on patients with mild to moderate Alzheimer's disease:

Namenda™ (Memantine HCI) Mild to Moderate Alzheimer's Disease Studies Reported Today; Forest Laboratories to Seek Approval for Mild to Moderate Indication By Mid-Year

... Forest Laboratories Inc. announced that results of a U.S., Phase III study of Namenda™ (memantine HCI) as monotherapy in mild to moderate Alzheimer's disease show the drug demonstrated ***a statistically significant difference versus placebo with respect to the study's primary efficacy measures of cognition and global outcome.... Forest plans to seek approval for a mild to moderate indication based on the positive outcome of the U.S. study.***

94. Forest's unexpected announcement that Namenda, which had ***failed*** an earlier mild/moderate Alzheimer's disease test, had now proved efficacious for this purpose and thus,

according to Forest, would likely be approved for treatment for all stages of Alzheimer's disease in a reasonably short timeframe, greatly increasing the revenue and profit potential for the drug for Forest, sent analysts following Forest into a frenzy.

95. On 1/7/04, *Bloomberg* reported:

Forest Says Drug Has New Use in Study; Shares Rise

Forest Laboratories, Inc., less than two months after shipping its first U.S. memantine treatment for advanced Alzheimer's disease, said the drug eased less severe symptoms in a study. ***The shares jumped a record 14 percent.***

Forest plans to use the research to request U.S. approval at mid-year for a new use of the drug in earlier stages of the disease, said Charles Triano, a spokesman for the company. Memantine, called Namenda in the U.S., is the only drug approved for treating moderate to severe Alzheimer's.

Approval for use in all Alzheimer's patients could double memantine's revenue potential to \$1 billion annually, said Hemant Shah, an analyst at HKS & Co., Inc. New York-based Forest is counting on the drug as it faces possible generic rivals for its top-selling Lexapro and Celexa antidepressants.

"This really expands the market," said Hemant.

* * *

Forest's shares rose \$8.81 to \$70.52 as of 4:16 p.m., their biggest one-day percentage gain since they began trading on the New York Stock Exchange in 1999.

96. On 1/7/04, Deutsche Bank issued a report on Forest:

Forest Laboratories, Inc.

New Namenda Results in Mild to Moderate Alzheimer's Increases Peak Sales Potential

* * *

- Forest announced positive results from a six-month Phase III trial of Namenda as monotherapy in patients with mild to moderate Alzheimer's disease. As a result, Forest expects to file a supplemental New Drug Application with the FDA in mid-2004 to seek an expanded label for Namenda, which was approved last October for the treatment of moderate to severe Alzheimer's.

- *In light of today's news, we now believe that peak sales of Namenda could top \$1B, versus our prior conservative peak sales forecast of \$500M, as the company now has the formal data to support Namenda as a treatment for the entire spectrum of Alzheimer's, from mild to moderate to severe. There are an estimated 4.4M Alzheimer's patients in the U.S., the majority of whom suffer from mild to moderate forms of the disorder, implying at least a doubling of the theoretical market opportunity for Namenda.*

97. On 1/7/04, J.P. Morgan issued a report on Forest:

Forest Laboratories, Inc.

Delightful Upside: Mild-Moderate Namenda P3 Successful

* * *

- *Unexpectedly positive news this morning out of Forest that its Phase III label expansion trial with Namenda in mild-moderate Alzheimer's Disease was successful. . . .*

... This one study is sufficient to file to file [sic] an sNDA in mid-2004 for a label expansion from the current indication of moderate-severe Alzheimer's to also include mild-moderate patients.

* * *

- *This should provide another substantial lift for the stock as we, and much of the market, had been assuming that the study would not demonstrate statistical significance based on the previous two failed studies.*

98. On 1/7/04, Prudential Equity Group issued a report on Forest. It stated:

FRX: NAMENDA DATA REMOVES RISK, STRENGTHENS PRODUCT PROFILE

* * *

HIGHLIGHTS

- *New positive data on Namenda in patients with mild-to-moderate Alzheimer's Disease (AD) strengthens product profile and removes risk from the FRX story.*

99. On 1/13/04, Forest announced that Namenda was now available nationwide. Its release stated:

Namenda™ (memantine HCl), First Drug Approved for Treatment of Moderate to Severe Alzheimer's Disease Now Available Nationwide

... Forest Laboratories, Inc. announced today that Namenda(TM) (memantine HCl), the first and only medication approved for patients with moderate to severe Alzheimer's disease, ***is now available*** to physicians, patients, and pharmacies nationwide. . . .

100. On 1/20/04, Forest reported its 3rdQ F04 results via a release stating:

Howard Solomon, Chairman and Chief Executive Officer of Forest, said: "During this quarter several important events occurred for Forest. We received Food and Drug Administration approval for Namenda™ for the treatment of moderate to severe Alzheimer's disease ***We also reported positive results from a placebo-controlled study of Namenda in the treatment of mild to moderate Alzheimer's disease which will serve as the basis of a potential label expansion.***"

101. On 1/20/04, Forest held a conference call during which the following transpired:

[Triano:] By way of a Safe Harbor Statement, let me add that various remarks that we may make about future expectations, plans and prospects for the company constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and actual results may be different.

* * *

[Goodman:] . . . ***[W]e reported a positive study outcome for our mild to moderate monotherapy study for Namenda which will support a supplemental New Drug Application for that indication around the middle of the year. This is meaningful as it could lead to Namenda being the only approved product for the entire spectrum of Alzheimer's patients. . . . Namenda was shipped during the quarter and pharmacies are now fully stocked. While we will not begin detailing the product until March 1st, physicians have begun prescribing the product and early prescription data is encouraging.***

We continue to focus on ***upgrading patients*** from Celexa to Lexapro and during the past three months have introduced to physicians several comparative clinical studies in depression of Lexapro versus the main competitive products in the category, Effexor, Zoloft and Celexa. . . . ***Upgrading patients from Celexa to the superior Lexapro and making Lexapro the standard of care for the treatment of both depression and anxiety remains a priority for us through 2004.***

* * *

[Tim Chang, Schroeder Analyst:] Okay. And what else do you need to do to file the supplemental NDA for Memantine for mild to moderate Alzheimer's disease, are you done with the trials?

[Goodman:] Trials are done. *We basically just have to put the package together for all of the trials that have been done from mild to moderate and file that and that's probably a six month process to get that filing done.*

102. As a result of these extraordinarily favorable representations during the Fall of 03, *i.e.*, that Lexapro was sufficiently superior to Celexa to justify a premium price and sufficiently different in pharmacological composition and action to justify its own patent protection and period of marketing exclusivity; that Forest was successfully transitioning huge numbers of Celexa patients to Lexapro because of its superior performance; that Lexapro was as effective as Zoloft, which had recently been reported by Pfizer to be beneficial to adolescents without any increase in suicidality; that Memantine/Namenda had been approved by the FDA for prescription to moderate/severe Alzheimer's disease patients and had now proven efficacious in a study for mild/moderate Alzheimer's disease patients, which would lead to an sNDA and anticipated FDA approval, Forest stock soared to its highest levels in history, skyrocketing from \$41.85 on 8/20/03 to a Class Period closing high of \$77.59 on 1/26/04 – an 85% increase in the stock price and a \$13-\$14 billion increase in market value in just five months. *As Forest's stock soared higher, Forest's insiders resumed their insider bail-out, selling some 2.9 million shares of their Forest stock for almost \$200 million between 10/03-2/04, including 1.78 million shares for \$133 million at \$72-\$77.42 per share in 1/04-2/04, as Forest's stock traded near its highest prices in history.*

103. However, just as Forest's stock hit its all-time high, a series of negative revelations began to come out that contradicted Forest's prior positive statements, assurances and representations, exposing its prior improper, manipulative and illegal conduct. On 1/29/04,

Forest revealed that it had received a subpoena from the Inspector General, U.S. Office of Personnel Management, for documents related to Celexa. The Office of Personnel Management is the federal government's human resources agency overseeing health benefits for some 10 million federal employees and retirees. On 1/29/04, Morgan Stanley issued a report on Forest, stating: "*According to management, the request was specifically for marketing materials . . .*"

104. On 1/30/04, *Reuters* reported:

James Sheehan, Assistant U.S. Attorney in Philadelphia, said Wyeth, Johnson & Johnson and Forest Laboratories, Inc., have been subpoenaed in a probe relating to a potentially over-aggressive marketing of psychiatric drugs.

"The office of the inspector general gets involved when there's fraud, when you cross over to misleading, deceptive or false statements or when there are kickbacks involved in connection with the marketing," he said.

* * *

The subpoenas came from the Inspector General for the U.S. Office of Personnel management [the main watchdog for federal health programs to ensure the beneficiaries of its program get the drugs they pay for and are treated with the right drugs for their condition], which investigates potential fraud *involving the health benefits of about 10 million federal employees and retirees.*

105. Then, just a few days later, on 2/2/04, an FDA panel held hearings on the connection between SSRI drugs and suicidality. On 2/3/04, *The New York Times* reported:

A scientific advisory panel urged the Food and Drug Administration on Monday to *issue stronger warnings to doctors now about the possible risks to children of a newer generation of antidepressant drugs, rather than wait until the agency's review of the drugs was completed.*

* * *

Dr. Thomas Laughren, the team leader for the F.D.A.'s division of neuropharmacological drug products, said that the agency took the panel's recommendation "*very seriously*" and that it *would probably issue such a warning "sooner rather [than] later."*

* * *

About 11 million prescriptions for a group of newer antidepressants were written for American children under 18 in 2002, according to the F.D.A.

106. On 1/26/04, Forest's stock had hit its all-time and Class Period high of \$77.90, closing at \$77.59. However, the partial revelations and adverse publicity of 1/29/04 and 2/2/04 caused Forest's stock to fall to as low as \$72.75 as the artificial inflation in the stock's price, caused by defendants' prior false statements, concealments and misconduct, began to come out of the stock as the truth began to enter the market.

107. On 2/23/04, *just eight days before Forest's 3/1/04 formal marketing launch of Memantine/Namenda for moderate/severe Alzheimer's disease*, Forest again *voluntarily publicized* the results of the new successful mild/moderate Memantine/Namenda test it had already publicized on 1/7/04. This was done to impress investors and analysts and to further condition the physician-prescribing community for Forest's promotion of Memantine/Namenda for off-label use, *i.e.*, for mild/moderate Alzheimer's, and so that its salesforce would have materials to direct or refer physicians to, or to leave with physicians to get them to prescribe Memantine/Namenda "off-label" for mild/moderate Alzheimer's. The Forest study indicated that Memantine/Namenda was efficacious for mild/moderate Alzheimer's disease patients and that therefore Forest would file an sNDA for that use by mid-04. Making this study public just before the nationwide marketing launch of Memantine/Namenda enabled Forest's specialty salesforce to promote the prescription of Memantine/Namenda for mild to moderate Alzheimer's disease, thus greatly boosting the apparent initial success of the drug upon its introduction and Forest's revenue and profits from that drug going forward. The 2/23/04 Forest release stated:

Researchers Report Namenda™ Provides Significant Benefits as Monotherapy to Patients With Mild to Moderate Alzheimer's Disease

... Forest Laboratories, Inc. announced that data from the first U.S. clinical trial evaluating Namenda™ (memantine HCl) as ***monotherapy*** for the treatment of mild to moderate Alzheimer's disease were presented for the first time today at the American Association for Geriatric Psychiatry (AAGP) annual meeting in Baltimore, Maryland. In this study, patients treated with Namenda

performed significantly better than patients who received placebo on both primary outcome measures of cognition and global functions. . . .

“These results are good news for the Alzheimer’s community because they suggest that using Namenda in the early stages of Alzheimer’s disease may translate into a patient’s ability to perform tasks such as communicating with caregivers or remembering names and phone numbers for longer periods of time compared to their ability if they did not receive treatment,” said Elaine Peskind, M.D., an investigator on the study and Professor, Department of Psychiatry and Behavioral Sciences, University of Washington School of Medicine. “As Namenda has a mechanism of action distinct from the currently approved treatments for mild to moderate Alzheimer’s disease and a favorable safety and tolerability profile, it promises to give physicians, caregivers, and patients a new and different treatment option for mild to moderate Alzheimer’s disease based upon FDA approval in the future.”

* * *

Based on the positive results of this study, Forest Laboratories plans to submit to the U.S. Food and Drug Administration (FDA) a supplemental New Drug Application for a mild to moderate Alzheimer’s disease indication for Namenda in mid-2004.

108. In early 3/04, Forest announced the formal launch of Memantine/Namenda via a press release and other public relations communications. As a result, Forest’s stock was pushed back up to \$77.28 by 3/5/04.

109. In late 3/04, further adverse publicity emerged regarding the association of SSRI antidepressant drugs, including Celexa/Lexapro, with increased suicidality. On 3/22/04, the FDA issued a health advisory warning regarding SSRI drugs and suicidality. On 3/23/04, *The New York Times* reported:

REGULATORS WANT ANTIDEPRESSANTS TO LIST WARNING

Patients taking antidepressants can become suicidal in the first weeks of therapy, and physicians should watch patients closely when first giving the drugs or changing dosages, federal regulators said yesterday.

The warnings are part of a public health advisory issued by the Food and Drug Administration and are a reminder that antidepressants, taken by millions around the world, are not without risks. The agency is asking drug manufacturers to place detailed caveats about the drugs’ side effects prominently on their labels.

* * *

Some psychiatrists said the new warnings were likely to slow sales, which amounted to about \$12 billion worldwide in 2002, and would change how the drugs were prescribed.

* * *

Dr. Regina Casper, a professor of psychiatry at Stanford, said that family physicians had become far too confident in the drugs' safety. . . .

"I think this will have a real sobering effect among family practice doctors," Dr. Casper said.

* * *

While suicide is already mentioned in a rarely read portion of a sheet included with prescriptions for the antidepressants, the new discussion of suicide will be placed in the drug's warning section, the most important, widely read and prominent section of the label. To further ensure that doctors will read the material, part of it will be in boldface. The label is the primary way the F.D.A. communicates with physicians about the safety and efficacy of drugs.

* * *

The drugs in the warning are: . . . *Celexa and Lexapro, from Forest Laboratories*
. . . .

Forest's stock continued to decline upon these adverse revelations.

110. On 3/23/04, H. Lundbeck issued a release stating:

Lundbeck's development director says that for many years it has included a warning that patients should be monitored for suicide risk in product descriptions for its antidepressants sold in Denmark. This statement comes in the wake of a demand by the FDA that a number of antidepressants sold in the US, including Lundbeck's, should be accompanied with such a warning. *Up until now there has been no warning with Lundbeck's antidepressants sold on the American market by its partner Forest Laboratories.*

111. On 4/20/04, Forest reported its 4thQ F04 and F04 results via a release stating:

Forest Laboratories, Inc. . . . today reported revenues and earnings for its fiscal fourth quarter and twelve months ended March 31, 2004.

* * *

Howard Solomon, Chairman and Chief Executive Officer of Forest, said: "The just completed fiscal year was highlighted by strong performance from our antidepressant category led by our SSRI Lexapro and by the recent launch of Namenda, an NMDA receptor antagonist for the treatment of moderate to severe Alzheimer's disease. For the year Lexapro sales surpassed the \$1 billion mark and now account for more than two-thirds of the new prescription market share for our franchise. We anticipate further significant growth for this product and our franchise, which currently has the leading market share in the category, as physicians continue to gain experience with and upgrade patients to Lexapro."

"The launch of Namenda this past quarter for moderate to severe Alzheimer's disease has been notable for the rapid early adoption of the product by physicians and resulting significant market share gains. Namenda's distinct mechanism of action, favorable side effect profile and unique indication in the moderate to severe disease category will continue to drive use

112. On 4/20/04, Forest held a conference call for Forest shareholders, analysts, money managers and the financial media, during which the following transpired:

[Triano:] By way of a Safe Harbor Statement, let me add that various remarks that we may make about future expectations, plans and prospects for the Company constitute forward-looking statements with the meaning of the Private Securities Litigation Reform Act of 1995 and actual results may be different.

* * *

[Goodman:] *Namenda has exceeded our early projections. We are very pleased with the early read we have on the launch.* Although the product has been available in pharmacies since January we did not begin *active detailing and sampling until March 1*, and have already seen a broad spectrum of patients utilizing the product. . . . We have noted a broad early acceptance by primary care physicians, in addition to neurologists and psychologists.

* * *

Also regarding Namenda we anticipate submitting a supplemental New Drug Application for mild to moderate Alzheimer's disease late this summer

113. The statements made by Forest or on behalf of Forest between 1/04-4/04 were false and misleading when made in their own right and for failing to disclose the following adverse facts necessary to make the statements made not misleading:

- (a) Forest was aware of a large multi-year study of Celexa for treating childhood/adolescent depression performed by Lundbeck with Forest's knowledge, consent and input, which showed that Celexa was not efficacious in that population and produced increased suicidality.
- (b) Lexapro was not superior to or more efficacious than Celexa in treating depression in adults 18 years or older, at least to any extent sufficient to justify the huge price disparity between Lexapro and generic Celexa.
- (c) Forest was improperly promoting and marketing Celexa and Lexapro for an off-label use, *i.e.*, treating depression in children/adolescents under the age of 18, which was artificially boosting the sales of Celexa and making the introductory prescriptions for and sales of Lexapro appear more successful than they would have been absent this improper off-label promotion and marketing.
- (d) Forest was improperly promoting and marketing Memantine/Namenda for an off-label use, *i.e.*, treatment of mild to moderate Alzheimer's disease, which was artificially boosting the initial prescriptions for and sales of Memantine/Namenda, making the introduction of that product appear more successful than it really was.
- (e) Forest knew it would not be able to submit an sNDA for Memantine/Namenda to the FDA to treat mild to moderate Alzheimer's by mid-04, as represented, because Forest had two negative studies showing no efficacy for Memantine/Namenda for mild/moderate Alzheimer's disease and the positive data in Forest's

possession did not indicate sufficient efficacy for the drug for that use to obtain FDA approval for Memantine/Namenda in treating mild/moderate Alzheimer's disease, in light of those negative studies.

(f) Forest did not promptly release clinical studies or tests on its drugs, but rather, concealed and did not release or publicize negative studies on Celexa/Lexapro, while going to great lengths to release and publicize favorable Celexa/Lexapro studies that were contradicted by the concealed studies.

(g) Forest knew from internal data, as well as other materials available to it, that the drugs Celexa/Lexapro were associated with increased suicidality in all user populations, *i.e.*, children, adolescents and adults, but concealed this information while promoting and marketing those drugs to those populations and representing them to be well-tolerated in those populations.

(h) Forest's reported successful financial results were due, in material part, to Forest's promotion and marketing of Lexapro and Celexa for childhood/adolescent use and Memantine/Namenda for mild/moderate Alzheimer's and physicians prescribing those drugs for those off-label uses.

(i) The positive physician response Forest reported it was seeing in connection with the introduction of Lexapro was due, in part, to Forest promoting and marketing the drug for childhood and adolescent use and physicians prescribing it for that use.

(j) To the extent Forest had compared Lexapro to Celexa for treating depression, it found that Lexapro had no materially greater beneficial effect in treating depression, but concealed this from both the physician-prescribing community and the investment community.

(k) Forest was not only positioning Lexapro with physicians as the SSRI of choice for new patients, non-responsive patients and patients suffering recurrent episodes of depression, but also for the initial treatment of children and adolescents suffering from depression.

114. On 4/23/04, *Bloomberg* reported on a just-completed major study by British medical authorities linking SSRI drugs to increased suicidality and condemning drug companies, including Forest, for concealing studies they performed and/or had showing that SSRIs had no beneficial impact on depressed children/adolescents and, in fact, increased suicidality in that population:

Antidepressants Are Risky for Children, Lancet Says

* * *

Unpublished findings showed that Paxil, Pfizer Inc.'s Zoloft, Wyeth's Effexor and Forest Laboratories, Inc.'s Celexa were less effective, had more side effects or raised the risk of suicide more than reported in published studies, the Lancet study said. . . .

"In view of the high risk of suicide in this group of children and young people, the possibility that a drug might increase that risk without clear evidence of benefit, should discourage its use," researchers from the U.K. National Collaborating Center for Mental Health said.

* * *

A Lancet editorial said *the lack of unfavorable data published about these medicines and children is "an abuse of the trust patients place in their physicians."*

"The story of research into selective serotonin reuptake inhibitor use in childhood depression is one of confusion, manipulation and institutional failure," said the editorial published in the April 23 Lancet.

Antidepressant sales reached \$19.5 billion last year worldwide, and are the third best-selling medicines in the U.S., behind cholesterol-reducers and ulcer drugs, according to IMS Health Inc. Pfizer's Zoloft had worldwide sales of \$3.4 billion.

* * *

“When you find that a drug company is withholding data because it will damage market share, when you’re talking about children with a high risk of suicide, that is potentially very serious,” lead researcher Tim Kendall said in a telephone interview. “Why aren’t they publishing it?”

* * *

Zoloft’s unpublished data from two published trials with 376 children suggested the drug was less effective than reported in a published study, and may have increased suicide thoughts and attempts, the study said. *Celexa, in two unpublished trials involving 422 children, didn’t reduce depression symptoms enough to show a benefit and raised the risk of suicide attempts and side effects, the researcher said.*

115. On 4/23/04, *The Wall Street Journal* reported:

Adding to a growing chorus, a respected British medical journal today is publishing a study *questioning the safety of prescribing most antidepressants to children.*

Researchers writing in the Lancet are the latest experts to raise alarms that Antidepressants may in some cases push children and adolescents toward suicide.

After reviewing published and unpublished data from drug-company trials of the effects on children of a certain class of drugs known as selective serotonin reuptake inhibitors, or SSRIs, six British university researchers concluded that only fluoxetine, known by the brand name Prozac, *demonstrated benefits that outweighed the risks.*

* * *

Data on four other drugs suggested the risks of use could outweigh the benefits. Those drugs are paroxetine, sold as Paxil, from GlaxoSmithKline PLC; sertraline, or Zoloft, from Pfizer Inc.; *citalopram, or Celexa, from Forest Laboratories, Inc.*; and venlafaxine, sold as Effexor by Wyeth. Effexor is a serotonin and norepinephrine reuptake inhibitor, which works somewhat differently than the SSRIs.

* * *

Most of the unpublished drug trials examined by the British researchers held more negative conclusions about Antidepressants than the published trials did.

The researchers criticized the abundance of unpublished data, saying that *“nonpublication of trials, for whatever reason, or the omission of important data from published trials, can lead to erroneous recommendations for treatment.”*

116. In order to try to counter adverse publicity and differentiate Celexa/Lexapro from other SSRI depression drugs and suicidality, Forest arranged for *The American Journal of Psychiatry* to publish the study Forest had conducted in mid-01 – and publicized in 12/01, 5/02, 7/02, 9/02 and 12/02 – showing that Celexa/Lexapro was efficacious in treating adolescent depression without adverse side effects. However, within days after the 6/04 edition of *The American Journal of Psychiatry* was issued, *The New York Times* published an explosive story that this Forest-sponsored *American Journal of Psychiatry* article had failed to include or present a much larger, more comprehensive study conducted by Forest/Lundbeck during 96-02 involving 422 children/adolescents, which demonstrated that Celexa was not efficacious for adolescent depression, that it actually increased suicidality, that Forest had concealed this study from *The American Journal of Psychiatry*, and that Forest/Lundbeck had not previously publicly released or publicized this adverse study. As a huge public uproar erupted over this deception by Forest, British health authorities demanded that Lundbeck/Forest surrender the secreted Celexa adolescent study and Forest stock continued to plummet.

117. *The New York Times* 6/21/04 article reported:

The issue of *The American Journal of Psychiatry* that hit the desks of its 37,000 readers this month reported test results for the antidepressant drug Celexa, ***indicating it could help children and teenagers.***

Before publication, the article received the kind of scrutiny common among medical journals. The study's authors had been asked to divulge their financial ties, if any, to the drug's marketer, Forest Laboratories, Inc., which sponsored the clinical trial. And the report was sent to reviewers who examined the trial methodology and checked to make sure that the article reflected other relevant research about the use of antidepressants in youngsters.

But neither the article nor the 27 scholarly footnotes that accompanied it mentioned another major drug-industry-sponsored trial completed in 2002, which found that Celexa did not help depressed adolescents any more than a placebo. Nor would the article's reviewers have been likely to find any clues of that trial's existence. The results of that trial were first noted last year on a single line of a chart that appeared on Page 96 of a textbook – one written in Danish.

* * *

In written responses to inquiries from The New York Times, Forest stated that the negative Celexa test, sponsored by a related company, was not mentioned in the recent article because "there was no citable public reference for the authors to examine."

But drug makers often announce trials with positive results without waiting for the results to be published. Forest, for example, issued a news release three years ago that highlighted the outcome of the positive Celexa trial. That was shortly after the test's completion, when the findings were first presented at a medical conference, but before the study was even submitted to The American Journal of Psychiatry for consideration. Three of the authors of the Celexa drug article in this month's issue are Forest employees.

* * *

The Celexa trial in question was run in Europe from 1996 to 2002 and was sponsored by H. Lundbeck, the Danish company that developed the drug.

* * *

A spokesman for Lundbeck said the company reported the trial results to Forest, although he could not say when. Forest executives did not respond to written inquiries from The Times seeking that information.

118. On 6/22/04, *The Wall Street Journal* reported:

Depression Trial Details Are Sought – Issue of Unpublished Studies Grows as U.K. Seeks Data From Study of Celexa, Kids

A team of British health officials that is developing guidelines for treating childhood depression asked Danish pharmaceutical company H. Lundbeck AS yesterday for details of an unpublished study on an antidepressant it makes.

The researchers, from Britain's National Collaborating Centre for Mental Health, said they are trying to find out why the study went unpublished. The study examined the safety and efficacy in children of the drug citalopram, which is sold in Europe under the brand Cipramil by Lundbeck. In the U.S., the drug is sold under the brand name Celexa by Forest Laboratories, Inc.

The request comes amid a swirling debate over the use of antidepressants in young people and a controversy over results of studies that have gone unpublished.

Forest's stock continued to decline in light of this adverse publicity.

119. On 6/22/04, Credit Suisse First Boston reported:

- Forest Labs [sic] recent pullback *surrounds recent controversies over pediatric clinical studies in the depression area and recent disclosures by Celexa's developer, Denmark's Lundbeck . . . from publishing a clinical study showing a lack of efficacy in pediatric patients groups.*

* * *

- *. . . [A]dverse publicity is also having an adverse effect on depression growth trend. Recent depression monthly new prescription activity has slowed from +4-5% during late 2003 to a recent flattening in the April-June period.*

120. On 6/22/04, J.P. Morgan reported:

We think Forest is weak for two reasons: 1) press attention analogous to the fall-out of Glaxo's Paxil trials in adolescents, which showed a suicide signal; and 2) a predictably consistent slowing SSRI/SNRI market growth.

121. On 6/23/04, Wells Fargo Securities reported on Forest:

- *We attribute the \$4.64 (7.6%, versus 0.36% for the S&P 500) decline in the share price of Forest Laboratories on Tuesday, June 22, to action by a British group requesting the data from a European Celexa study conducted by Lundbeck in depressed patients aged 18 years or under that demonstrated a lack of effect for the drug.*

122. Now that Forest had been exposed as concealing adverse Celexa/Lexapro studies, it was forced to reveal another negative Lexapro study. On 6/24/04, Forest issued a release:

Forest Laboratories, Inc. Announces Results of Recently Completed Lexapro(R) Pediatric Depression Clinical Trial

Forest Laboratories, Inc. announced today the results of a recently completed placebo-controlled study of Lexapro® (escitalopram oxalate) in children and adolescents. *Patients receiving Lexapro did not demonstrate statistically significant separation from placebo in the primary efficacy measure*

....

While Forest said this study was just “recently completed,” that was not true. The study had been completed earlier and was being concealed. “*They are clearly responding to investor concerns*” about media reports and European regulatory concern over companies ignoring negative results, said Deborah Knobelman, an analyst at ThinkEquity Partners.

123. On 6/26/04, *The New York Times* reported:

Forest Laboratories has said a recently concluded test found that its antidepressant Lexapro did not help depressed children and adolescents, an announcement that comes amid the growing controversy over clinical drug tests.

The company's announcement is significant because Lexapro contains essentially the same active ingredient as another Forest antidepressant, Celexa, which is widely prescribed for pediatric use.

Forest's stock price continued to fall to as low as \$57.10 on 6/28/04 as more artificial inflation came out of the stock, as more truth entered the market.

124. On 6/29/04, Eliott Spitzer, the Attorney General of New York, requested that Forest provide all documents regarding concealed clinical trials or tests and "off-label" promotional activities for its drugs – a request which followed a highly-publicized action by Spitzer's office against GlaxoSmithKline for improper if not fraudulent marketing of its SSRI drug – Paxil – for adolescent use and its concealment of studies it had performed or had showing Paxil did not work with adolescents and increased suicidality.

125. On 6/29/04, *Bloomberg* reported:

Forest Laboratories Inc., the maker of Namenda Alzheimer's disease drug, *said the New York state attorney general's office requested any information the company may have about off-label clinical trials and product promotions.*

The request states that State Attorney General Eliot Spitzer is concerned about whether the company may have violated New York law, Forest said in a statement. The request isn't a subpoena and New York-based Forest said it would cooperate.

Spitzer's press office declined to comment. His request to Forest comes *less than a month after he filed a lawsuit accusing GlaxoSmithKline Plc of withholding negative trial results on the use of the antidepressant Paxil to treat children, which the company denies.*

126. On 6/29/04, *Reuters* reported:

Forest Labs says NY AG seeks documents on marketing

. . . Forest Laboratories Inc. said on Tuesday that New York's Attorney General is concerned that the company may be violating state law by promoting its products for unapproved uses, *sending its stock lower in after-hours trading.*

The New York-based drugmaker said Attorney General Eliot Spitzer requested "any information that may exist with respect to off-label clinical trials or promotion of its products."

127. On 6/30/04, Prudential Equity Group issued a report on Forest:

* News of the Spitzer inquiry not that surprising *given the fact that several of FRX's competitors have been crying fowl [sic] for a long time on what is sometimes purported to be aggressive marketing practices. The allegations are that FRX does not follow the industry-adopted PhRMA guidelines that spell out what can and can't be done when marketing drug products.*

128. On 6/30/04, *The New York Times* reported:

Forest Asked to Supply Information on Marketing of Some Drugs

Forest Laboratories said yesterday that it had received a wide-ranging request from the New York attorney general, Eliot Spitzer, asking for information about how the company tested and promoted drugs like its antidepressant Celexa for so-called off-label, or as yet-unapproved, uses.

A representative of Mr. Spitzer's office, who asked not to be identified, said that the request covered 10 products sold by Forest. *But that person said that Mr. Spitzer is particularly interested in how Forest tested and promoted two of its antidepressants, Celexa and Lexapro, which are widely used off-label by doctors for the treatment of pediatric depression.*

* * *

Mr. Spitzer's action follows by a week an article in *The New York Times* which disclosed that Forest did not tell a medical journal about a failed, unpublicized trial of Celexa in children and adolescents when it published an article this month about a positive trial of the same drug in the same type of patients. Some of the article's authors were Forest employees.

On 6/30/04, Forest's stock fell to as low as \$54.97, as further artificial price inflation came out of the stock.

129. On 7/6/04, Natexis Bleichroeder Inc. issued a report on Forest. It stated:

* We have lowered our revenue and EPS estimates for Forest ***to reflect the recent weakness in the anti-depression market.***

130. On 7/16/04, SG Cowen issued a report on Forest. It stated:

Reduced Estimates Reflect More Cautious Outlook For Lexapro

Conclusion: Reflecting a more cautious view on the multiple fundamental pressures facing Forest's antidepressant franchise, ***dominated by the slowing antidepressant market trends . . . we have reduced our Lexapro sales projections for F2005-2008.***

131. On 8/5/04, *The Wall Street Journal* reported:

FDA Revisits Issue of Antidepressants for Youths – New Analysis May Pressure Agency to Set Limit on Use Because of Suicide Risk

A new Food and Drug Administration analysis of clinical-trial data shows evidence of a link between antidepressant drugs and suicidal tendencies among young people. . . .

The new analysis, which focused on 25 studies of nine drugs, found that children and teenagers who took the medicines were more likely to have behavior or thoughts that appeared suicidal, compared with those who got placebo pills.

* * *

The new findings are likely to intensify pressure on the agency to consider stronger action to limit use of the drugs by young people.

* * *

The document, dated July 19, focuses on an array of antidepressant drugs including Pfizer, Inc.'s Zoloft, Forest Laboratories Inc.'s Celexa, Wyeth's Effexor, GlaxoSmithKline PLC's Wellbutrin and Paxil, and Prozac, made by Eli Lilly & Co. and available generically.

132. By 9/1/04, investors and analysts realized that despite Forest's prior representation that it would file an sNDA for Memantine/Namenda for the treatment of mild/moderate Alzheimer's disease by mid-04, Forest had not filed the sNDA and thus Memantine/Namenda would not be approved for active marketing or sale for use in patients with mild/moderate Alzheimer's disease, ***at least not in the timeframe that Forest had previously indicated,*** thus restricting the available market for that drug and the potential Forest revenues

and profits from that drug. Later, Forest did file an sNDA for Memantine/Namenda for mild/moderate treatment of Alzheimer's, but the application was denied by the FDA as the drug did not produce statistically significant results.

POST CLASS PERIOD EVENTS

133. On 9/7/04, Forest issued a release that it was settling its dispute with New York Attorney General Spitzer:

Forest Laboratories Announces Adoption of On-line Registry for Clinical Studies; Attorney General Agrees to Close Inquiry

... Forest Laboratories, Inc. today announced that it will establish a publicly available, on-line Clinical Trial Registry containing summaries of key Forest-sponsored clinical studies completed since January 1, 2000 for drugs which Forest currently markets. The creation of the Clinical Trial Registry is also part of an agreement reached today with the New York State Attorney General. As a result of Forest's adoption of the Clinical Trial Registry, the Attorney General has agreed to end his inquiry of Forest's clinical study disclosure practices.

* * *

This will include summaries of clinical study reports for clinical studies of the use of Celexa and Lexapro by pediatric patients. These summaries will include results for the protocol-defined efficacy and safety outcomes, as well as a description of the trial design and methodology.

134. On 9/14/04, Thomas Weisel Partners issued a report on Forest. It stated:

Executive Summary

* A joint FDA panel discussed antidepressant (AD) use and the potential for suicidality in pediatric patients. Nine ADs were discussed, including Forest's Celexa. . . .

* The panel voted 25-1 that ADs may increase the risk of suicidality in pediatric patients and 27-0 that they are unable to conclude at this time that any single AD agent is free from risk of suicidality. ***Additionally, the group voted 18-5 in favor of a black box warning.***

135. On 6/13/05, the Centers for Medicare & Medicaid Services (CMS), a Federal agency within the U.S. Department of Health and Human Services, reported that henceforth

Medicare formularies need only include Celexa (citalopram) *or* Lexapro (escitalopram) because they are essentially identical. By way of explanation, CMS stated that “[e]ither escitalopram or citalopram may be left off formularies since escitalopram is the component of citalopram that is responsible for the antidepressant effect.”

136. On 7/26/05, the FDA issued a non-approvable letter to Forest, denying its application to expand the approved uses of Namenda to include moderate-to-severe Alzheimer’s, confirming that the study it submitted to the FDA was never as conclusive as defendants represented.

INSIDER TRADING

137. During the Class Period, Forest’s insiders owned and sold the following Forest shares:

<u>Name</u>	<u>Date</u>	<u>Shares</u>	<u>Price</u>	<u>Proceeds</u>	<u>% Sold</u>
Eggers	6/10/04	36,000	\$61.910	\$ 2,228,760	59%
	6/10/04	24,008	\$61.910	\$ 1,486,335	
	6/10/04	<u>10,960</u>	\$61.910	<u>\$ 678,534</u>	
		70,968		\$ 4,393,629	
Goodman	5/12/03	400,000	\$49.540	\$ 19,816,000	11%
	5/12/03	<u>100,000</u>	\$49.700	<u>\$ 4,970,000</u>	
		500,000		\$ 24,786,000	
Hochberg	10/22/02	20,456	\$50.000	\$ 1,022,800	73%
	10/25/02	134,000	\$48.080	\$ 6,442,720	
	1/22/04	45,000	\$72.000	\$ 3,240,000	
	1/22/04	<u>24,000</u>	\$72.000	<u>\$ 1,728,000</u>	
		223,456		\$ 12,433,520	
Olanoff	10/22/02	69,056	\$50.020	\$ 3,454,181	69%
	2/10/04	201,728	\$74.950	\$ 15,119,514	
	2/10/04	<u>66,472</u>	\$74.950	<u>\$ 4,982,076</u>	
		337,256		\$ 23,555,771	
Prehn	5/22/03	11,000	\$50.000	\$ 550,000	88%
	7/29/03	10,000	\$48.000	\$ 480,000	
	10/23/03	1,000	\$50.700	\$ 50,700	

<u>Name</u>	<u>Date</u>	<u>Shares</u>	<u>Price</u>	<u>Proceeds</u>	<u>% Sold</u>
	10/24/03	32,000	\$50.500	\$ 1,616,000	
	1/28/04	12,000	\$76.400	\$ 916,800	
	1/28/04	<u>9,600</u>	\$76.400	<u>\$ 733,440</u>	
		75,600		\$ 4,346,940	
Solomon	10/22/02	712,080	\$49.940	\$ 35,561,275	37%
	10/22/02	170,000	\$49.690	\$ 8,447,300	
	10/23/02	517,920	\$48.020	\$ 24,870,518	
	10/27/03	300,000	\$50.360	\$ 15,108,000	
	10/28/03	400,000	\$50.090	\$ 20,036,000	
	10/29/03	359,000	\$49.940	\$ 17,928,460	
	10/30/03	41,000	\$50.060	\$ 2,052,460	
	2/11/04	100,000	\$76.020	\$ 7,602,000	
	2/12/04	300,000	\$75.630	\$ 22,689,000	
	2/13/04	200,000	\$74.450	\$ 14,890,000	
	2/13/04	100,000	\$74.290	\$ 7,429,000	
	2/17/04	350,000	\$74.400	\$ 26,040,000	
	2/18/04	<u>250,000</u>	\$74.630	<u>\$ 18,657,500</u>	
		3,800,000		\$221,311,514	
Stafford	10/1/02	80,000	\$44.330	\$ 3,548,400	50%
	1/26/04	<u>75,000</u>	\$77.200	<u>\$ 5,790,000</u>	
		155,000		\$ 9,336,400	
Triano	1/23/04	20,000	\$74.570	\$ 1,491,400	100%
TOTALS:		\$5,182,280		\$301,655,174	

NO SAFE HARBOR

138. Forest's verbal "Safe Harbor" warnings accompanying its oral forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability for several reasons. First of all, Forest, in its Class Period conference calls and other meetings with analysts and investors, never warned that any "particular" statement was an FLS, stating only that presentations "may" or "will" contain FLS. Second, Forest never referenced in connection with its oral FLS any SEC filing or other publicly available documents that contained cautionary statements, as required. Finally, the cautionary statements in Forest's SEC filings were not "meaningful;" rather, they were *boilerplate*, even though the economic,

industry and company-specific factors affecting Forest's business and its performance varied markedly during 01-04, the purported cautionary statements contained in Forest's 10-Q and 10-K filings with the SEC (incorporated herein by reference) were word-for-word identical – the substance of those warnings never changed, even though Forest's business, products and the economic and competitive environment in which it operated was constantly changing.

139. Each of Forest's 10-Q reports issued during 00, 01, 02, 03 and 04 contained the following identical language:

Forward Looking Statements

Except for the historical information contained herein, the Management Discussion and other portions of this Form 10-Q contain forward looking statements that involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products and the risk factors listed from time to time in the Company's filings with the SEC, including the Company's Annual Report on Form 10-K for the fiscal year ended March 31, [2004].

140. Each of Forest's 10-K reports for 00, 01, 02 and 03 contained the following identical language:

Forward Looking Statements

Except for the historical information contained herein, the Management Discussion and other portions of this annual report contain forward looking statements that involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products and the risk factors listed from time to time in the Company's filings with the SEC, including the Company's Annual Report on Form 10-K for the fiscal year ended March 31, [2004].

141. Thus, the statutory safe harbor provided for FLS does not apply to the false FLS pleaded. The defendants are liable for the false FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false and the FLS was authorized and/or approved by an executive officer of Forest who knew that the FLS was false. None of the historic or present

tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

CLASS ACTION ALLEGATIONS

142. This is a class action on behalf of purchasers of Forest common stock during the Class Period. Excluded from the Class are officers and directors of the Company, as well as their families and any entity controlled by any of them. Class members are so numerous that joinder of them is impracticable.

143. Common questions of law and fact predominate and include whether defendants: (i) violated the 1934 Act; (ii) omitted and/or misrepresented material facts; (iii) knew or recklessly disregarded that their statements were false; and (iv) artificially inflated the price of Forest common stock and the extent of and appropriate measure of damages.

144. Plaintiffs' claims are typical of those of the Class. Prosecution of individual actions would create a risk of inconsistent adjudications. Plaintiffs will adequately protect the interests of the Class. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

COUNT I

For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants

145. Plaintiffs repeat the allegations contained above.

146. During the Class Period, defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did deceive the investing public, including plaintiffs and other Class members, as alleged in this complaint and caused plaintiffs and other members of the Class to purchase Forest stock at artificially inflated prices. In furtherance of this unlawful scheme and course of conduct, defendants, and each of them, took the actions set forth in this Complaint.

147. Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's common stock in an effort to maintain artificially high market prices for Forest stock in violation of §10(b) of the 1934 Act and Rule 10b-5. All defendants are sued as primary participants in the wrongful and illegal conduct charged in this complaint.

148. These defendants employed devices, schemes and artifices to defraud. While in possession of material adverse non-public information, they engaged in acts, practices, and a scheme as alleged herein in an effort to assure investors of Forest's business and financial success and prospects for continued substantial growth. This included the making of, or the participation in the making of, untrue statements of material fact and concealing facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading.

149. This conduct artificially inflated the price of Forest stock and operated as a fraud and deceit upon the purchasers of Forest stock during the Class Period, proximately causing damage to the class members when Forest stock suffered statistically significant, company-

specific declines as the truth entered the market, exposing defendants' prior misrepresentations and other fraudulent conduct – stock declines that were not due to general market movements, industry conditions, changed investor expectations or other company-specific information unrelated to the alleged fraud.

150. The defendants had actual knowledge of the misrepresentations and omissions of material facts set forth in this Complaint, or acted with severe reckless disregard of the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them.

151. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Forest stock was artificially inflated during the Class Period. Relying directly or indirectly on the false and misleading statements made by defendants or upon the integrity of the market in Forest stock, plaintiffs and the other members of the Class purchased Forest stock during the Class Period at artificially high prices and were damaged thereby and as the stock price declined as specified herein, due to a series of partial revelations by which the truth entered the market over time, resulting in a significant stock price decline.

152. At the time of defendants' misrepresentations and omissions, plaintiffs and other members of the Class were ignorant of their falsity. Had plaintiffs and the other members of the Class and the market known the truth which was not disclosed by defendants, plaintiffs and other members of the Class would not have purchased their Forest stock, or, if they had acquired such stock during the Class Period, they would not have done so at the artificially inflated prices which they paid, or suffered the damages they did when the stock price declined for specific reasons related to the fraud, proximately causing Class members' damages.

153. As a direct and proximate result of defendants' wrongful conduct, plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's stock during the Class Period.

COUNT II

For Violation of §20(a) of the 1934 Act Against Defendants Forest, Solomon and Goodman

154. Plaintiffs repeat the allegations contained above.

155. Individual Defendants Solomon and Goodman acted as controlling persons of Forest within the meaning of §20(a) of the 1934 Act as alleged in this complaint. By virtue of their high-level executive positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations, accounting policies and methods, and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, these Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which plaintiffs contend are false and misleading. Individual Defendants Solomon and Goodman were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

156. In particular, each of these Individual Defendants had direct and supervisory involvement in the day-to-day operations, and in the accounting policies and practices of the Company and, therefore, each is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged in this Complaint, and

exercised the same. The Company controlled all the Individual Defendants and all of its employees.

157. As set forth above, defendants each violated §10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, defendants Solomon, Goodman and Forest are liable pursuant to §20(a) of the 1934 Act. As a direct and proximate result of defendants' wrongful conduct, plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's stock during the Class Period.

II

For Violation of §20A of the 1934 Act Against Defendants Solomon, Hochberg, Stafford and Prehn

158. Plaintiffs repeat the allegations contained above. This Count is brought pursuant to §20A of the 1934 Act on behalf of all purchasers of Forest common stock during the Class Period.

159. Defendants Solomon, Hochberg, Stafford and Prehn, by virtue of their positions as officers and directors of Forest, had access to, and were in possession of, material non-public information about Forest at the time they sold millions of shares of Forest common stock during the Class Period.

160. By virtue of their participation in the scheme to defraud investors described in Count I and their sale of stock while in possession of material, non-public information about Forest, defendants violated §10(b) of the 1934 Act and applicable rules and regulations thereunder.

161. The chart below details defendant Solomon's sales of Forest common stock made contemporaneously with plaintiff's purchases of shares of Forest common stock:

Date Sold	Shares	Plaintiff	Purchase/Settlement Date	Shares
10/27/03	300,000	Teamsters Affiliates Pension Plan	10/29/03	100
		Teamsters Affiliates Pension Plan	10/29/03	200
10/28/03	400,000	Teamsters Affiliates Pension Plan	10/29/03	1,500
10/29/03	359,000	Teamsters Affiliates Pension Plan	11/03/03	200
		Teamsters Affiliates Pension Plan		
		Teamsters Affiliates Pension Plan		
10/30/03	41,000	Teamsters Affiliates Pension Plan		

162. The chart below details defendant Hochberg's sales of Forest common stock made contemporaneously with plaintiff's purchase of Forest common stock:

Date Sold	Shares	Plaintiff	Purchase/Settlement Date	Shares
01/22/04	45,000	UNITE H.E.R.E.Staff Retirement Fund	01/23/04	1,500
01/22/04	24,000	UNITE H.E.R.E.Staff Retirement Fund		

163. The chart below details defendant Stafford's sales of shares of Forest common stock made contemporaneously with plaintiff's purchase of shares of Forest common stock:

Date Sold	Shares	Plaintiff	Purchase/Settlement Date	Shares
01/26/04	75,000	UNITE H.E.R.E. Staff Retirement Fund	01/29/04	1,300

164. The chart below details defendant Prehn's sales of shares of Forest common stock made contemporaneously with plaintiffs' purchases of shares of Forest common stock:

Date Sold	Shares	Plaintiff	Purchase/Settlement Date	Shares
10/23/03	1,000	Teamsters Affiliates Pension Plan	10/28/03	100
10/24/03	32,000	Teamsters Affiliates Pension Plan	10/28/03	200
		Teamsters Affiliates Pension Plan	10/28/03	2,000
		Teamsters Affiliates Pension Plan	10/29/03	100
		Teamsters Affiliates Pension Plan	10/29/03	200
		Teamsters Affiliates Pension Plan	10/29/03	1,500
01/28/04	12,000	UNITE H.E.R.E. Staff Retirement Fund	01/29/04	1,300
01/28/04	9,600	UNITE H.E.R.E. Staff Retirement Fund		

165. Plaintiffs and all other members of the Class who purchased shares of Forest common stock contemporaneously with sales of Forest common stock by defendants: (i) have suffered substantial damages because, in reliance on the integrity of the market, they paid artificially inflated prices for Forest common stock as a result of the violations of §10(b) of the 1934 Act and Rule 10b-5 as alleged in Count I; and (ii) would not have purchased Forest common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially inflated by defendants' false and misleading statements and concealment. At the time of the purchases by plaintiffs and the other members of the Class, the fair and true market value of the Forest common stock was substantially less than the price paid by them.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs pray for relief and judgment, as follows:

- A. Determining that this action is a proper class action, certifying plaintiffs as class representatives under Rule 23 of the Federal Rules of Civil Procedure and designating this Complaint as the operable complaint for class purposes;
- B. Awarding compensatory damages in favor of plaintiffs and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- C. Awarding extraordinary, equitable and/or injunctive relief as permitted by law, equity and the federal statutory provisions sued hereunder, pursuant to Rules 64 and 65 and any appropriate state law remedies to assure that the Class has an effective remedy;
- D. Awarding plaintiffs and the Class their costs and expenses incurred in this action, including counsel fees and expert fees; and
- E. Awarding such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury.

DATED: August 12, 2005

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